



Clinical Pharmacology Fellowship Handbook

(Revised 25 February 2009)

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**Walter Reed Army Institute of Research and Uniformed Services University of the Health Sciences
Clinical Pharmacology Fellowship Training Program**

Clinical Pharmacology Fellowship Training Program Acknowledgement Form

Fellow: _____

Fellow's Start Date: _____ Fellow's Graduation Date: _____

The following certifies that I, _____ ,
(Fellow's Name)
acknowledge receipt of the following fellowship materials:

Material(s) Received	Date Received	Fellow's Initials
<i>Clinical Pharmacology 2nd Edition</i> by Atkinson		
<i>Principles and Practices of Clinical Research 2nd Edition</i> by Gallin		
<i>Melmon and Morelli's Clinical Pharmacology</i> by Carruthers et al		
<i>Clinical Pharmacokinetics</i> by Rowland & Tozer		
<i>Basic and Clinical Pharmacology</i> by Katzung		
<i>Ethical and Regulatory Aspects of Clinical Research</i> by Emanuel		
Fellow Agreement		
Fellowship Handbook (to include Appendices)		
WRAIR Due Process Memo		
Command Policy 2002-33 Clearance of Professional Manuscripts		

Fellow: _____

Director: COL Colin Ohrt, MD, MPH

WALTER REED ARMY INSTITUTE OF RESEARCH GRADUATE MEDICAL EDUCATION PROGRAM & THE LONG TERM HEALTH EDUCATION TRAINING PROGRAM

FELLOW AGREEMENT

This agreement represents administrative guidelines and a contract between the Walter Reed Army Institute of Research (WRAIR) and the graduate medical education program/long term health education training program Fellow.

1. Each Fellow will be provided a written description of the Graduate Medical Education (GME)/Long Term Health Education Training (LTHET) experience to be undertaken.

2. Fellow's Responsibilities: The fellow who is enrolled in GME/LTHET will:

- A. Participate fully in the educational activities of the specific program and, as required, assume responsibility for teaching and supervising other fellows, house staff, and students.
- B. If in GME, participate in safe, effective, and compassionate patient care under supervision commensurate with his/her level of advancement and responsibility.
- C. Develop a program of self-study and professional growth with guidance from the teaching staff.
- D. Adhere to established practices, procedures, and policies of the institution, and participate in quality assurance activities.
- E. Develop an understanding of ethical, socioeconomic, and legal issues that affect GME/LTHET and the practice of medicine.
- F. Provide, at least annually, a critique of the training program and individual faculty members' performance for review by the program director.
- G. Inform him- or herself of the Program Requirements for his/her educational program, as specified in the Clinical Pharmacology Fellowship Handbook at the time of matriculation into the program, and to work with the faculty of his/her program to achieve substantial compliance with these Program Requirements.
- H. Serve if requested on institutional committees and councils whose actions affect his/her education and/or patient care.

3. Benefit to Fellows:

A. The opportunity to receive GME/LTHET with increasing levels of responsibility, in accordance with increasing knowledge and skills.

B. Financial Support: The Fellow will receive pay and allowances according to his/her entitlement as a commissioned officer in his/her respective uniformed service.

C. Vacations/Professional Leave/Sick Leave: Program-specific leave policies are contained in the Fellowship Handbook. The Fellow understands that, in the case of illness or pregnancy, his/her status as a Fellow will not be adversely affected for that reason. The Fellow further understands that decisions concerning extension of his/her fellowship due to illness or pregnancy will be determined by the faculty in conjunction with the Fellowship Director, based on the requirements established by the ABCP and the Army.

D. Liability Insurance: Medical Officers are covered by the provisions of 10 USC 1089, which renders the officer immune from the personal liability or damages arising out of any act of professional negligence alleged to have been committed while acting within the scope of employment as a Medical Officer in a uniformed service. Thus, as fellows are considered employees of the United States government, the provisions of 10 USC 1089 will immunize them from individual tort liability. When performing out-service training rotations in non-federal institutions, the training must be part of the fellow's official government duties and there must be a properly executed memorandum of understanding (MOU) between the WRAIR and the nonfederal institution before the fellow can participate. Without the MOU, the fellow may not be covered by 10 USC 1089 and may not be immune from personal liability.

E. Hospital and Health Insurance for Fellows and their Families: As uniformed service officers, fellows will receive hospitalization and medical treatment in military medical treatment facilities. Their family members may receive care in military facilities in accordance with Tricare policies or, as TRICARE beneficiaries, in civilian institutions. Counseling for psychological or chemical dependency problems is available for all uniformed service personnel and their civilian beneficiaries.

F. Living Quarters: Military housing is not generally available in the Walter Reed area. As uniformed service officers, fellows are entitled to consideration for military housing. Fellows not eligible for military housing, or for whom military housing is not available, will receive a Variable Housing Allowance in accordance with the respective uniformed service's pay and allowances policy.

G. Term of Fellowship: The term of the fellowship will be the period of time established for the duration of academic and practical training that is consistent with national standards. The period of GME/LTHET is indicated on the uniformed service orders issued to each Fellow. Acceptance of these orders constitutes the Fellow's agreement to remain on active duty for the period of the obligated service (approximately 2 years for both GME/LTHET). Extensions of training require the approval of the Fellow's respective uniformed service. Continuation in the program will be for the expressed period unless the Fellow:

1. fails to maintain an acceptable level of performance (including personal behavior) and/or competence and requires an extension of training;
2. requires excessive time out of training (e.g. convalescent leave);
3. fails due course selection for promotion to the next higher officer grade on two successive occasions, in which case training may, at the option of the Fellow's uniformed service, be discontinued;
4. is terminated from training as a result of adverse action taken in accordance with WRAIR Policy on Due Process for Participants in Professional Education and Training Programs memo; dated March 09.
5. requires excessive time out of training such that prior, continuous time in training is invalidated for purposes of board certification eligibility;
6. is discharged from the military service for disciplinary or administrative reasons. Termination of the educational program under these conditions is not subject to the due process procedures of AR 351-3.

H. Off-Duty Employment: Fellows will adhere to the policy as stated in the Fellowship Handbook. In unusual cases, requests for exceptions to this policy will be considered and must be fully explained in a letter addressed to the Commander, WRAIR.

I. Call Schedule and Schedule of Assignments: These will be provided to Fellows by their respective program directors or the program director's representative. Fellows will be informed of policies regarding call schedules and assignments and the times when schedules will be published.

J. Guarantee of Due Process: The Fellow will be provided a performance evaluation at least semi-annually, and a Fellow Training File will be maintained. For specific problems, remedial non-adverse action may be taken. Adverse action may be taken with due process afforded in accordance with WRAIR Policy letter on Due Process for Participants in Professional Education and Training Programs memo; dated March 09.

K. Discrimination and Harassment: The WRAIR will afford an environment free of discriminatory intimidation whether based on sex, race, religion, color, age, national origin, marital status, or handicapping condition. Information, informal counseling, and guidance on filing formal complaints regarding sexual harassment or other forms of discrimination or intimidation will be provided. The Walter Reed Army Medical Center Equal Employment Opportunity (EEO) Office is available for assistance on all such matters.

L. Reappointment: Fellows are appointed to WRAIR fellowship positions for the period specified in writing by the fellow's supporting service. Fellows who voluntarily leave the training program or who are released for inadequate performance may be reappointed by reapplying through their supporting service. Fellows who are granted a leave of absence from their training program do not require reappointment. These fellows will resume their fellowship duties at a time and in a manner agreed upon in writing by the Fellowship Director and the fellowship, with the concurrence of the fellow's supporting service.

M. Licensure: The GME fellow will comply with IC 103 to AR 40-68, "fellows are required to have in their possession a current, valid, and unrestricted professional license upon completion of the PGY-2 year." Exceptions are granted only for those applying for a license in a state that requires two full years of training prior to issuance. Failure to do so will be reason for adverse personnel actions in accordance with policies of the fellow's uniformed service. These may include probation, loss of special pays and benefits, reclassification, and/or involuntary separation.

N. Advancement: Advancement from year 1 to year 2 is contingent on satisfactory performance and compliance with all administrative requirements including licensure and height/weight and physical fitness standards. Failure of satisfactory performance after selection for PGY-2 training may result in removal from training by board action at the MEDCOM level.

O. Special Pay: Physician Fellows should strongly consider signing the four-year contract before matriculating into the program.

Signature of Fellow/Date

Signature of Fellowship Director/Date

CF: Fellow



Clinical Pharmacology Fellowship

Fellow's Folder Index & Required Documentation in Sections

Fellow: _____

Fellow's Start Date: 1 July 2009 Fellow's Graduation Date: 30 June 2011

Beginning of Binder

Required Document	In Binder (Y or N)
Clinical Pharmacology Acknowledgement Form	
Copy of Fellow's Agreement	

Section 1: CV & Credentials

Required Document	In Binder (Y or N)
CV	
Current Copy of License (for GME Fellow)	
Copy of Medical Degree (for GME Fellow)	
Copy of Residency Certificate (for GME Fellow)	
Copy of Primary Board Certification (for GME Fellow)	
Copy of Basic Life Support Certificate (for GME Fellows)	
Copy of Privilege Status Information for NNMC (for GME Fellow)	
Copy of Privilege Status Information for WRAMC (for GME Fellow)	
Copy of PhD/PharmD Diploma (or transcript) (for LTHET Fellow)	

Section 2: Courses/Certifications

Required Document	In Binder (Y or N)
Certificate of Completion: Principles of Clinical Pharmacology	Completion Date: May 10
Certificate of Completion: Statistics 500M I	Completion Date: December 09
Certificate of Completion: CITI Human Participant Protection	By end of Summer: 2009
Certificate of Completion: Good Clinical Practices Course	By end of Summer: 2009
Cert of Complete: Intro to Principles & Practices of Clin Research	Completion Date: Spring 11
Cert of Complete: Ethical & Regulatory Aspects of Human Subjects Research	Completion Date: Spring 11
Modern Drug Analysis (Fellow Documentation)	Continuous Documentation
Graduation Certificate	Completion Date: June 11

Not Required (but Recommended) Documentation	In Binder (Y or N)
Certificate of Completion: Tufts Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation	
Certificate of Completion: Topics in Clinical Trials (FDA)	Completion Date: Spring 11

Section 3: Consults/Rotations

Required Document	In Binder (Y or N)
Consult Schedule: First Year	
Consult Schedule: Second Year	
First Year Consult Record #1	
First Year Consult Record #2	
First Year Consult Record #3	
First Year Consult Record #4	
First Year Consult Record #5	
First Year Consult Record #6	
First Year Consult Record #7	
First Year Consult Record #8	
First Year Consult Record #9	
First Year Consult Record #10	
Second Year Consult Record #1	
Second Year Consult Record #2	
Second Year Consult Record #3	
Second Year Consult Record #4	
Second Year Consult Record #5	
Second Year Consult Record #6	
Second Year Consult Record #7	
Second Year Consult Record #8	
Second Year Consult Record #9	
Second Year Consult Record #10	
FDA Rotation Documentation (objectives accomplished)	Completion Date: Spring 11
Army Pharmacovigilance Center Rotation Documentation (objectives accomplished)	
National Capital Area Poison Control Center Rotation Documentation (objectives accomplished)	
Clinical Pharmacology Unit (or Clinical Trials Unit) Rotation (or Directors' Approval to forego this requirement due to research project) (objectives accomplished)	

Not Required (but Recommended) Documentation	In Binder (Y or N)
2 nd Clinical Pharmacology Unit (or Clinical Trials Unit) Rotation (or Directors' Approval to forego this requirement due to research project) (objectives accomplished)	

Section 4: Teaching/Presentations

Required Document	In Binder (Y or N)
Letter (or schedule) indicating Fellow volunteered as Instructor/Co-Instructor in USUHS Medical Student Clin Pharm Course for First Year	Completion Date: December 09
Letter (or schedule) indicating Fellow volunteered as Instructor/Co-Instructor in USUHS Medical Student Clin Pharm Course for Second Year	Completion Date: December 10
Abstract Acknowledgement of Submission for ASCPT (or ASTMH)	
Abstract Submitted (ASCPT or ASTMH)	
First Year Journal Club Presentation (or Article) that you facilitated with	
Second Year Journal Club Presentation (or Article) that you facilitated with	

Section 5: Evaluations

Required Document	In Binder (Y or N)
Evaluation of Fellow by Directors: July 09 – December 09	Completion Date: December 09
Evaluation of Fellow by Directors: January 10 – June 10	Completion Date: June 10
Evaluation of Fellow by Directors: July 10 – December 10	Completion Date: December 10
Evaluation of Fellow by Directors: January 11 – June 11	Completion Date: June 11
Fellow's Activity Log: July 09 – December 09 (<i>Fellow Provides</i>)	Completion Date: December 09
• Morning Report Information (<i>Ed Spec Inputs</i>)	Completion Date: December 09
• Research Information (<i>Ed Spec Inputs</i>)	Completion Date: December 09
• Weekly Journal Club Information (<i>Ed Spec Inputs</i>)	Completion Date: December 09
• Teaching Activity Information (<i>Ed Spec Inputs</i>)	Completion Date: December 09
• Conferences/Meeting Attended (<i>Ed Spec Inputs</i>)	Completion Date: December 09
• Other Activities Information (<i>Ed Spec Inputs</i>)	Completion Date: December 09
Fellow's Activity Log: January 10 – June 10 (<i>Fellow Provides</i>)	Completion Date: June 10
• Updated Morning Report Information (<i>Ed Spec Inputs</i>)	Completion Date: June 10
• Updated Research Information (<i>Ed Spec Inputs</i>)	Completion Date: June 10
• Updated Weekly Journal Club Information (<i>Ed Spec Inputs</i>)	Completion Date: June 10
• Updated Teaching Activity Information (<i>Ed Spec Inputs</i>)	Completion Date: June 10
• Updated Conferences/Meeting Attended (<i>Ed Spec Inputs</i>)	Completion Date: June 10
• Updated Other Activities Information (<i>Ed Spec Inputs</i>)	Completion Date: June 10
Fellow's Activity Log: July 10 – December 10 (<i>Fellow Provides</i>)	Completion Date: December 10
• Updated Morning Report Information (<i>Ed Spec Inputs</i>)	Completion Date: December 10
• Updated Research Information (<i>Ed Spec Inputs</i>)	Completion Date: December 10
• Updated Weekly Journal Club Information (<i>Ed Spec Inputs</i>)	Completion Date: December 10
• Updated Teaching Activity Information (<i>Ed Spec Inputs</i>)	Completion Date: December 10
• Updated Conferences/Meeting Attended (<i>Ed Spec Inputs</i>)	Completion Date: December 10
• Updated Other Activities Information (<i>Ed Spec Inputs</i>)	Completion Date: December 10
Fellow's Activity Log: January 11 – June 11 (<i>Fellow Provides</i>)	Completion Date: June 11
• Updated Morning Report Information (<i>Ed Spec Inputs</i>)	Completion Date: June 11
• Updated Research Information (<i>Ed Spec Inputs</i>)	Completion Date: June 11
• Updated Weekly Journal Club Information (<i>Ed Spec Inputs</i>)	Completion Date: June 11
• Updated Teaching Activity Information (<i>Ed Spec Inputs</i>)	Completion Date: June 11
• Updated Conferences/Meeting Attended (<i>Ed Spec Inputs</i>)	Completion Date: June 11
• Updated Other Activities Information (<i>Ed Spec Inputs</i>)	Completion Date: June 11

Section 5: Evaluations (cont)

Evaluation of Fellow by Mentor/Faculty		
Fellow's Evaluation of Mentor/Faculty (MAJ Bennett)	In Faculty Binder (Y or N)	
Fellow's Evaluation of Mentor/Faculty (MAJ Leary)	In Faculty Binder (Y or N)	
Fellow's Evaluation of Mentor/Faculty (COL Magill)	In Faculty Binder (Y or N)	
Fellow's Evaluation of Mentor/Faculty (COL Miller)	In Faculty Binder (Y or N)	
Fellow's Evaluation of Mentor/Faculty (COL Ohrt)	In Director Binder (Y or N)	
Fellow's Evaluation of Mentor/Faculty (Dr. Cantilena)	In Director Binder (Y or N)	
Fellow's Evaluation of Rotation (FDA)	Completion Date: Spring 11	
Fellow's Evaluation of Army Pharmacovigilance Center Rotation		
Fellow's Evaluation of National Capital Area Poison Control Center Rotation		
Fellow's Evaluation of Rotation (Clin Pharm Unit)		
Fellow's Oral Presentation Evaluation	Completion Date: December 09	
Fellow's Final Oral Presentation Evaluation	Completion Date: Spring 11	
Fellow's Annual Program Evaluation	Completion Date: Spring 10	
Fellow's End of the Program Evaluation	Completion Date: Spring 11	

Not Required (but Recommended) Documentation

In Binder (Y or N)

Fellow's Evaluation of Rotation (Clin Pharm Unit #2)	
Fellow's Oral Presentation Evaluation for 2 nd Project	
Fellow's Final Oral Presentation Evaluation for 2 nd Project	

Section 6: Transcripts/Exams

Required Document

In Binder (Y or N)

Exam: Pharmacology PHO 2001 #1 (for Fellows who Audit the Course)	Completion Date (if auditing): Summer 10
Exam: Pharmacology PHO 2001 #2 (for Fellows who Audit the Course)	Completion Date (if auditing): Summer 10
Exam: Pharmacology PHO 2001 #3 (for Fellows who Audit the Course)	Completion Date (if auditing): Summer 10
Exam: Pharmacology PHO 2001 #4 (for Fellows who Audit the Course)	Completion Date (if auditing): Summer 10
USUHS Medical Student Pharmacology Course Grades (for Fellows who are required to attend the course)	Completion Date (if taking): June 10

Section 7: Project Information

Required Document

In Binder (Y or N)

Fellow's Research Project Approval Form by Directors	Completion Date: December 09
Completed Project	Completion Date: Spring 11
Submitted Publication	Completion Date: Spring 11

Not Required (but Recommended) Documentation

In Binder (Y or N)

Fellow's Research 2 nd Project Approval Form by Directors	
Fellow's 2 nd Project Presentation	
2 nd Completed Project	

Section 8: Army Related Info

Required Document	In Binder (Y or N)
Memo re: GME or LTHET Acceptance	
Memo re: Acknowledgement of GME or LTHET Acceptance	
ORB	
OER: 1 st Year	
OER: 2 nd Year	

Section 9: Miscellaneous

Required Documentation	In Binder (Y or N)
Preclinical Drug Development Team Meeting Routine Participation/ Observation	
Clinical Drug Development Team Meeting Routine Participation/ Observation	
IRB/Human Use Review Committee Participation/Observation	
Pharmacy & Therapeutics Committee Participation	
Participation in National Clinical Pharmacology Society	

Clinical Pharmacology Fellowship

Timeline of Events

***This is by no means all inclusive. I recommend you use this as a guide, and still actively seek input from fellow Fellows, Staff, and Directors. If you see additions needed, please add and email them to the Educational Specialist for inclusion into the main document.*

July

- *First Year Fellow* - 1 July: Fellows start date for Fellowship
- *First Year Fellow* - 8 July until end of Summer: Orientation of Fellows
 - Date: 8 July until end of Summer
 - Location: WRAIR, USUHS
 - Time of Day: Anytime between 0800-1700
 - Possible Time Requirement: This will be a few hours to all day depending on the training session
- *First Year Fellow*: Register for Acquisition Training
- *First Year Fellow*: Register for CBRNE Training
- ALL/DIV ET: recruit speakers for Lecture Series
- Army Fellowship Director: General Recruitment - Market at Tropical Medicine Course @USUHS
- Army Fellowship Director: GME Recruitment - Talk for incoming ID/IM/Peds/General IM Residents/Fellows at WRAMC
- Ed Spec: Update Everyone's Property Pass
- Ed Spec: Get individuals business cards

August

- *First Year Fellow* - 1st Week: register for FAES- NIH Courses (Statistics for Biomedical Scientists (STAT 500M))
 - Date: September until December
 - Location: NIH, Bethesda
 - Time of Day: Tuesday or Wednesday evening
 - Possible Time Requirement: 3 hours every week (not including studying)
- *First Year Fellow* - 1st Week: register for Principles of Clinical Pharmacology (NIH)
 - Date: September until the end of April
 - Location: WRAIR or NIH, Bethesda (also, there are numerous remote locations, or a remote location can be developed at a site if there is someone there to proctor it)
 - Time of Day: Thursday nights
 - Possible Time Requirement: 1.5 hours (1830-1945) every week

August (cont.)

- *First Year Fellow* - 1st Week: register Ethics: CITI Human Participant Protections if needed
 - Date: August
 - Location: online course
 - Time of Day: at Fellow's discretion
 - Possible Time Requirement: a week to 2 weeks
- *First Year Fellow* - 2nd Week: research GCP Class, choose, and register
 - Date: August
 - Location: numerous locations
 - Time of Day: at Fellow's discretion (depending on course chosen)
 - Possible Time Requirement: potentially up to a week
- *First Year Fellow* - 2nd Week: register for SPSS Levels 1, 2, & 3 at WRAMC. If you need further information or are interested in attending, please contact 202-782-7878 or E-mail: DCISTATS@amedd.army.mil (NOT REQUIRED, but recommended)
- *First Year Fellow* - 2nd Week: If desire & money is available, register for Tufts' Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation (NOT REQUIRED, but recommended)
 - Date: February
 - Location: Boston, MA
 - Time of Day: 5-Day Course
 - Possible Time Requirement: 50 hours
- Second Year Fellow - 1st Week: register for Introduction to the Principles and Practice of Clinical Research (NIH)
 - Date: October to February
 - Location: NIH, Bethesda
 - Time of Day: typically on Monday or Tuesday evenings
 - Possible Time Requirement: 1.5 hours (1700-1830) every week
- Second Year Fellow - 1st Week: Start making arrangements for the FDA Rotation. Please refer to your handbook under FDA Section for more information.
 - Date: February to June
 - Location: White Oak Campus, Silver Spring (depending on choice of rotation)
 - Time of Day: typically during the work week from Monday to Friday
 - Possible Time Requirement: 8 hours per day for 2 to 4 months (depending on choice of rotation)
- Second Year Fellow - 2nd Week: register for Ethical and Regulatory Aspects of Clinical Research
 - Date: October to November
 - Location: NIH, Bethesda
 - Time of Day: Wednesday mornings
 - Possible Time Requirement: 3 hours (0830-1130) every week
- Second Year Fellow - Set up on Call Schedule for First and Second Year Fellows and submit to Dr. Cantilena for approval

August (cont.)

- First/Second Year Fellow: Attend Morning Report
 - Date: All year round depending on if you are on Call or Not
 - Location: NNMC or WRAMC
 - Time of Day: Monday and Wednesday mornings (NNMC)
 - Possible Time Requirement: 2 hours (0730-0930) every week
- First/Second Year Fellow: Present Consultation at the Educational Consultation Conference
 - Date: All year round depending on if you are on Call or Not
 - Location: USUHS
 - Time of Day: Typically on Thursdays
 - Possible Time Requirement: 2 hours (1330-1530) every week
- First/Second Year Fellow: Set up Rotation with Army Pharmacovigilance Center
 - Date: at Fellow's discretion
 - Location: TBD
 - Time of Day: at Fellow's discretion
 - Possible Time Requirement: 2-4 week rotation
- First/Second Year Fellow: Set up Rotation with National Capital Area Poison Control Center
 - Date: at Fellow's discretion in concurrence with Dr. Cantilena
 - Location: Washington DC
 - Time of Day: at Fellow's discretion in concurrence with Poison Control Center
 - Possible Time Requirement: 1 day per week for 1 month
- First/Second Year Fellow: Attend the following meetings throughout Fellowship
 1. Preclinical drug development meeting at WRAIR
 2. Clinical drug development at WRAIR
 3. P&T Committee meeting at WRAMC or NNMC
 4. HURC/IRB meeting at WRAIR
 - Date: at the Meeting Leader's discretion
 - Location: TBD
 - Time of Day: at the Meeting Leader's discretion, but during the work hours
 - Possible Time Requirement: 4 hours per week
- Fellowship Directors: General Recruitment - Recruit potential LTHET Fellows
- Army Fellowship Director: GME Recruitment - Talk for ID/IM/Peds/General IM Residents/Fellows/Staff at BAMC (in conjunction with consultants meeting in SAT; requests two month in advance)
- Ed Spec: Send updated Fellow information to Sandy Simpson/Denise Anderson/NCOIC/NCO
- Ed Spec: Talk to First Year Fellows about introducing Lecture Series Speakers
- Ed Spec: General Recruitment - ASCPT Conference (<http://www.ascpt.org/annualmeeting2010>)
 - When is it?
 - Booth Wanted?

- Does Army Program Director want to host a table at the Trainee Luncheon?

August (cont.)

- ALL: Ed Spec starts the process - Register for ASTMH Conference
 - Date: Typically in November/December
 - Location: Various Locations
 - Time of Day: Monday-Sunday
 - Possible Time Requirement: 60 hours
- ALL: Ed Spec starts the process - Register for ASCPT Conference
 - Date: Typically in March/April
 - Location: Various Locations
 - Time of Day: Monday-Sunday
 - Possible Time Requirement: 60 hours

September

- **Potential Fellows:** 15 September, GME Online Application Due
- *First Year Fellow* - First Year Fellows introduce Lecture Series Speakers
- *First/Second Year Fellow:* Contact Dr. Cantilena regarding CPU Rotation or COL Ohrt regarding CTU Rotation
 - Date: February to August (1st Year Fellow)/September to December (2nd Year Fellow)
 - Depends on availability of studies
 - Location: USUHS, CPU or WRAIR, CTU
 - Time of Day: typically during the work week from Monday to Friday
 - Possible Time Requirement: 8 hours per day for 2 to 4 months (depending on choice of rotation)
- *First/Second Year Fellow/Staff:* ASCPT Abstract Submission Due Date
 - Do not forget: Abstract must be submitted to MATS 2 weeks before the ASCPT deadline
 - Do not forget: Abstract must be submitted to WMIS 1.5 weeks before the ASCPT deadline
- Fellowship Directors: General Recruitment - 1st & 2nd Week: Interview Potential GME Fellows
- Ed Spec/Army Fellowship Director: GME Recruitment - Contact FP, AAP, APA, Army ACP and determine if someone can speak at their meetings about the Fellowship
- Ed Spec/Army Fellowship Director: Prepare the LTHET Request Form to be submitted by COL Lukey (currently)
 - The request for the update is generated by COL Lukey (currently)
- Ed Spec: order Office Supplies/Books/etc. for next years Fellows using what is left of P8 funds
- ALL - 1st Week until mid-December: Lecture Series for “first semester” starts
 - Date: September to the end of May
 - Location: WRAIR
 - Time of Day: Thursdays

- Possible Time Requirement: 1.5 hours

October

- *First Year Fellow - 2nd Week:* Contact Mr. Alonzo Cruder (301-295-3223) to register for USUHS Medical Student Pharmacology Course (audit unless you are a non-Physician Fellow, then depending on your background, you may be required to register)
 - Date: January to April
 - Location: USUHS
 - Time of Day: typically on Monday, Wednesdays, Fridays
 - Possible Time Requirement: 2 hours per day (this does not include studying)
- *First Year Fellow - 4th Week:* Submitted Research Proposal Form to Fellowship Directors
 - The Research Project is ongoing for all Fellows
- *Second Year Fellow:* Talk with Dr. Cantilena in regards to making arrangements to present your Research Information to the Department of Medicine at USUHS
 - Date: May
 - Location: USUHS
 - Time of Day: TBD
 - Possible Time Requirement: 1.5 hours
- *First/Second Year Fellow: 2nd Week:* Contact Dr. Cantilena (cell phone: 240-372-2146) regarding USUHS Medical Student Clinical Pharmacology Course (3rd and 4th year medical students)
 - Date: December
 - Location: USUHS
 - Time of Day: During the workday
 - Possible Time Requirement: 3-8 hours (this does not include preparation time)
- Fellowship Directors: GME Recruitment - Decide if you want to attend the FP Conference, register
- Army Fellowship Director - 4th Week: Input interview information into the GME Website about potential Fellows
- Army Fellowship Director: LTHET Recruitment - Contact LTC Bauer regarding the LTHET Message and make sure it has went forth.
- Ed Spec: General Recruitment - Talk with Army Fellowship Director and see if he would like to take Job/Fellowship announcements to the ASTMH as per previous years
- ALL/DIV ET: recruit speakers for Lecture Series

November

- **Potential Fellow:** 1 November, GME Supporting Documents due
- *First Year Fellow - 3rd Week/1st Week in December:* Oral Presentation of Research Project
- Army Fellowship Director: GME Recruitment - GME Board Selection in Washington DC (1 week long)
 - (<https://gme.gdit-conferences.com/>)
- Army Fellowship Director: GME Recruitment - Market at HPSP Annual Dinner Meeting
- Army Fellowship Director: LTHET Recruitment - Talk with contacts (Fellows, Co-Workers, etc.) and ask if they have any recommendations for potential Fellows

- Army Fellowship Director/Ed Spec: GME Recruitment - Arrange to talk with incoming ID/IM/Peds/General IM Residents/Fellows at WRAMC
- Ed Spec - 1st Week: Start setting up Fellows Evaluation (to be completed in December)

November (cont.)

- Ed Spec - 1st Week: Update folder indexes for Fellows and email them to let them know what they are missing
- Ed Spec - 1st Week: Reserve the Lecture Series Room (prefer 1W81 or 1W77) up until the end of June
- Ed Spec: GME Recruitment - FP Conference (<http://www.usafp.org/annual-meeting.htm>)
 - When is it?
 - Booth Wanted?
 - Who Attending?
- Ed Spec: GME Recruitment - AAP (PEDS) Conference
(<http://www.aap.org/sections/uniformedservices/default.cfm?jumpdown=yes#jumpdown>)
 - When is it?
 - Booth Wanted?
 - Who Attending?
- ALL: make Hotel Reservations for ASCPT Conference

December

- **Potential Fellow:** 15 December, GME Announces Candidates
- Second Year Fellow - 1st Week: register for Topics in Clinical Trials (Dr. Temple) (NOT REQUIRED, but HIGHLY recommended)
 - Date: February to June
 - Location: White Oak Campus, Silver Spring
 - Time of Day: Days Vary
 - Possible Time Requirement: Times Varies
- First/Second Year Fellow: Fellows' 6 month Evaluation
- First/Second Year Fellow: 1st Week: hand in Activity Log for Evaluation to Ed Spec
- Ed Spec: GME Recruitment - APA (Psych) Conference
(<http://www.psych.org/MainMenu/EducationCareerDevelopment/Meetings.aspx>)
 - When is it?
 - Booth Wanted?
 - Who Attending?

January

- First/Second Year Fellow: register if interested for John Hopkins Malaria Research Conference (NOT REQUIRED, but recommended)
- Ed Spec: Update the Handbook/PIF/Faculty/Director binder (this should be ongoing, but if major overhaul is needed, this is a nice time to).

- Ed Spec: Update the Annual Program Director's Vision Statement, then send out to everyone for consensus

January (cont.)

- Ed Spec: General Recruitment - Update all Recruitment Material and then (re)print all needed material
 - GME Brochure
 - LTHET Brochure
 - Combined (?) Brochure
 - Flyer
 - Big poster
 - News Articles:
 - US Medicine
 - Challenging Career Field for Army Docs
 - Military Action Against Malaria from Washington University
- Ed Spec: General Recruitment - Check WRAIR Website and update all needed information
- Ed Spec: General Recruitment - Check the following websites to make sure the Fellowship information is up-to-date
 - ASTMH:
 - Work on online advertisement
 - ASCPT:
 - <http://www.ascpt.org/education/fellow.cfm>
 - <http://www.ascpt.org/education/training.cfm>
 - Work on online advertisement
 - ABCP: <http://www.abcp.net/training.html>
 - FP Website: <http://www.usafp.org/> (under the Education/Research tab, then under Fellowships)
 - NEJM Website: work on online advertising
 - GME Websites:
 - Army (<http://www.mods.army.mil/MedicalEducation/>)
 - Navy (<https://nmmpte.med.navy.mil/gme/MCPP.htm>)
 - Airforce (http://airforcemedicine.afms.mil/idc/groups/public/documents/webcontent/knowledgejunction.hcst?functionalarea=AFPhysicianEducation&doctype=subpage&docname=CTB_047647)
 - HPSP
- Ed Spec: General Recruitment - Contact the following Newsletter to see if they can publish a piece about Clinical Pharmacology
 - GME Recruitment - USAFP: LtCol Leslie Knight (currently) - leslie.knight@yokota.af.mil or one can go to the website (<http://www.usafp.org/>) under Main Menu, then Newsletter and contact the editor.

- GME Recruitment - AAP: COL David Estroff (currently) - david.estroff@amedd.army.mil or you can go to the website (<http://www.aap.org/sections/uniformedservices/newsletter.htm>) and contact the editor.
- Ed Spec: LTHET Recruitment - Read the current MILPER Message and current paperwork is accurate

January (cont.)

- ALL - 2nd Week: Lecture Series for “second semester” begins
 - Date: September to the end of May
 - Location: WRAIR
 - Time of Day: Thursdays
 - Possible Time Requirement: 1.5 hours

February

- **Potential Fellow:** LTHET Information emailed by consultants to individuals in their AOC
- Army Fellowship Director: GME Recruitment - Talk for incoming ID/IM/Peds/General IM Residents/Fellows at WRAMC
- Ed Spec: start ordering Computers for new Fellows
- Ed Spec: Update Everyone’s Property Pass
- ALL: make Hotel Reservations for ASTMH Conference

March

- Second Year Fellow: Apply to take the ABCP Boards
- Second Year Fellow: Submit Research to a journal for Publication
 - Do not forget: Article must be submitted into MATS before submission into journal
 - Do not forget: Approval also must be secured from other organizations that contributed to the research, ex: Navy, GSK, etc.
- Fellowship Directors: Interview Potential LTHET Fellows
- Ed Spec: Start getting the Graduation Certificate done (1st: MAVS, 2nd: USUHS Signatures, 3rd: WRAIR Signatures)
- Ed Spec: GME Recruitment - Start preparing letter, envelope, and brochure for mailing to MC Officers
- Ed Spec: GME Recruitment - Remind Army Fellowship Director to contact Ms. Lavon Jolly (lavon.jolly@us.army.mil) for an Excel spreadsheet with the mailing addresses of all MC Officers between the ranks of CPT and LTC, so that we can send out our brochures for the Clinical Pharmacology Fellowship program

April

- **Potential Fellows:** 10 April, LTHET Applications must be postmarked or received by
- **Potential Fellows:** 20 April, LTHET Application Due
- Second Year Fellow: Submit Research to a journal for Publication
 - Do not forget: Article must be submitted into MATS before submission into journal
 - Do not forget: Approval also must be secured from other organizations that contributed to the research, ex: Navy, GSK, etc.

- Fellowship Directors: Recruit potential GME Fellows
- Army Fellowship Director - 1st Week, GME Recruitment: Submit request to Ms. Lavon Jolly (lavon.jolly@us.army.mil) for an Excel spreadsheet with the mailing addresses of all MC Officers between the ranks of CPT and LTC, so that we can send out our brochures for the Clinical Pharmacology Fellowship program

April (cont.)

- Army Fellowship Director - 4th Week: Submit LTHET Fellow recommendation to the LTHET Board
- Army Fellowship Director - GME Recruitment: Talk with contacts (Fellows, Co-Workers, etc.) and ask if they have any recommendations for potential Fellows
- Fellowship Directors/Staff: Start compiling a list of Project Opportunities for new Fellows
- Ed Spec: Start making arrangements to insure new Fellows have an Office Space
- Ed Spec: GME Recruitment - Army ACP Meeting (http://www.acponline.org/about_acp/chapters/army/)
 - When is it?
 - Booth Wanted?
 - Who Attending?

May

- *First Year Fellow*: Complete Harmon Clinical Pharmacology Test. Request tests from Ed Spec.
 - Date: End of May (unless you are a non-Physician Fellow who attended the course – you should be handing in your Pharmacology Test at the completion of each one that was taken during the course)
 - Location: at Fellow's discretion
 - Time of Day: at Fellow's discretion
 - Possible Time Requirement: at least 2 hours per test (8 hours)
- *First/Second Year Fellow/All*: ASTMH Abstract Submission Due Date
 - Do not forget: Abstract must be submitted to MATS 2 weeks before the ASTMH deadline
 - Do not forget: Abstract must be submitted to WMIS 1.5 weeks before the ASTMH deadline
- *First/Second Year Fellow*/Army Fellowship Director - 4th Week: Start working on OER/OER Support Form
- *Second Year Fellow* - 3rd Week: Oral Presentation of Research Project
- Army Fellowship Director: GME Recruitment - Proceed with Email marketing campaign to the following groups:
 - Primary Care Consultants
 - Other targeted Consultants
 - Primary Care ETS-ing
- Army Fellowship Director/Ed Spec: GME Recruitment - Arrange to talk with incoming ID/IM/Peds/General IM Residents/Fellows at WRAMC
- Army Fellowship Director/Ed Spec: GME Recruitment - Arrange to talk with ID/IM/Peds/General IM Residents/Fellows/Staff at BAMC (in conjunction with consultants meeting in SAT)
- Fellowship Directors: 5 May, LTHET Board meets
- Ed Spec – 1st Week: Start setting up Fellows Evaluation (to be completed in June)

- Ed Spec – 1st Week: Update folder indexes for Fellows and email them to let them know what they are missing
- Ed Spec: Prepare ABCP Annual Update for submission in July
- Ed Spec: Reserve the Lecture Series Room (prefer 1W81 or 1W77) up until the end of December
- Ed Spec: Start making arrangements for the Fellows Orientation
- Ed Spec: Make new binders for all incoming Fellows

May (cont.)

- Ed Spec: GME Recruitment - Get mailing out to all MC Officers between the ranks of CPT and LTC
- First/Second Year Fellow/Ed Spec: Ed Spec send Directors/Faculty/Annual Program evaluation to Fellows for Completion

June (cont.)

- First Year Fellow - 3rd Week until complete: In-process to WRAIR
- Second Year Fellow - 4th Week until complete: Out-process from WRAIR
- Second Year Fellow - 3rd Week: Graduation
- First/Second Year Fellow: Fellows' 6 month Evaluation
- First/Second Year Fellow: 1st Week: hand in Activity Log for Evaluation to Ed Spec
- First or Second Year Fellow: register for the US Military Tropical Medicine (MTM) Course. If you need further information or are interested in attending, please contact (301)295-5726 or E-mail: april.truett@med.navy.mil (NOT REQUIRED, but recommended)
 - Date: July
 - Location: USUHS
 - Time of Day: During the work day
 - Possible Time Requirement: 1 to 2 weeks
- Army Fellowship Director (if Consultant): Consultants Meeting in Texas (5 days long)
- Ed Spec: Talk with Army Fellowship Director to see if he would like to advertise at the Tropical Medicine Course in July at USUHS
 - A flyer was distributed in the previous years



American Board of Clinical Pharmacology, Inc.

Incorporated 1976

Administrative Office: P.O. Box 40278 • San Antonio, Texas 78229-1278 • (210) 567-8505 • FAX (210) 567-8509

May 26, 2004

Ralf Brueckner, MD, COL, MC, USA, Program Director
Walter Reed Army Institute of Research
Clinical Pharmacology Fellowship Program
503 Robert Grant Avenue
Silver Spring, Maryland 20910-7500

Dear Dr. Brueckner:

I am pleased to be able to tell you that the American Board of Clinical Pharmacology has agreed to accredit your program as of March 24, 2004. This accreditation is valid until March 24, 2009. An annual report to the Board indicating any areas of substantial change is to be submitted on the anniversary of your approval and should be submitted in summary form.

As you know, the importance of accreditation of your program is that graduates will meet the criteria to sit for the ABCP examination as long as the program is either registered or accredited.

If you have any questions, please let me know. Many congratulations and best wishes for the future for you and your program.

Sincerely,

A handwritten signature in black ink, which appears to read 'Alexander M. M. Shepherd'.

Alexander M. M. Shepherd, M.D., Ph.D.
Executive Director
American Board of Clinical Pharmacology, Inc.

abcp.net

I. General Fellowship Description

Founded in 1980 by Dr. Carl Peck, the WRAIR/USUHS Clinical Pharmacology Fellowship Training Program (the Program) trains individuals (military & civilian Fellows) to serve as clinical pharmacologists in academia; regulatory roles (e.g. FDA); government/military drug discovery and development; and the drug industry. The Program is available to active duty military physicians and non-physicians (primarily Army) and, through USUHS, it is also available to civilians. The Program is jointly ventured by (1) the F. Edward Hébert School of Medicine at the Uniformed Services University of the Health Sciences (USUHS), (2) the Walter Reed Army Institute of Research (WRAIR), and (3) the U.S. Food and Drug Administration (FDA), per the Memorandum of Understanding (MOU) dated 8 January 2008. Offered as a two year fellowship, the Program typically hosts 2-5 Fellows each year and is associated with major medical centers and teaching hospitals such as the Walter Reed Army Medical Center (WRAMC) and the National Naval Medical Center (NNMC). The curriculum includes several courses given at and by the National Institutes of Health (NIH). Additional educational experiences are available at other medical schools and institutes in the region. The Program is jointly run by a Program Director at both the USUHS and the WRAIR.

The U.S. Army's interest in sponsoring this joint Clinical Pharmacology Fellowship Training Program is to train clinical pharmacologists to serve in the Army's drug development programs, located in various institutions within the U.S. Army Medical Research and Materiel Command (USAMRMC). Army clinical pharmacologists also teach the Department of Defense's future physicians and non-physicians in areas such as rational therapeutics, evaluation of potential adverse events and drug interactions, and how to provide clinical pharmacology expertise in difficult therapeutic problems.

II. Resources

A. Faculty

The primary faculty includes clinical pharmacologists, other physicians, and scientists onsite at both the USUHS and the WRAIR. Other faculty are located at WRAMC, NNMC, and the FDA. Additionally, there are adjunct faculty from NIH, regional medical centers, and Industry. These faculty provide lectures, small group teaching experiences, supervision of clinical consultations, and mentorship of research.

During year one, the majority of the Fellow's interactions with the faculty will be in didactic training, clinical pharmacology consultation service, and developing and initiating a research project. During year two, a major portion of the Fellow's time will be spent with the research mentor conducting, analyzing, and reporting the Fellowship research project and rotating at the FDA.

**Note: For a complete listing of faculty members, please see the appendix entitled Contact Information.*

B. Computer & Reference Information

The Program will provide the Fellow with a computer, either desktop or laptop, and any required software. Certain software is available via network servers at WRAIR or USUHS. It is highly recommended, although not required, that a Fellow use a laptop. Since the Fellow spends his/her time at various locations and institutions, a laptop will enable the Fellow to access and work on data while away from the primary office or lab.

Each Fellow will be held responsible for the software and equipment entrusted to him/her while enlisted in the Program. This includes regular (daily – weekly) back-up of the non-application files (e.g. data, documents) from the computer's hard drive. This also includes being in compliance with the Property Pass Regulations (reference WRAIR Policy Letter, 04-10, Hand Receipt Holders Duties and Responsibilities, dated 02 April 2004, paragraph 16, section D, Property Removed from the Institute). At the conclusion of the Fellowship, the Fellow will return the computer and all software.

The Program will provide the Fellow with required textbooks, research supplies, and office supplies. The current textbooks include Atkinson's *Clinical Pharmacology 2nd Edition*; Gallin's *Principles and Practice of Clinical Research 2nd Edition*; S. George Carruthers, et al *Melmon and Morrelli's Clinical Pharmacology*; Rowland and Tozer's *Clinical Pharmacokinetics*; Katzung's *Basic and Clinical Pharmacology 10th Edition*; and Emanuel's *Ethical and Regulatory Aspects of Clinical Research*. Additional textbooks may be found in the Program library, located in the Fellows' office at the WRAIR (Room 1A28). Texts may be purchased by the Program as required, but must be placed in the Program library when the Fellow no longer requires them or at the completion of the Program. All purchases by the WRAIR Fellows must be approved by the WRAIR Director. Any Fellow may use his/her personal funds to purchase other resources as he/she chooses.

Complete medical libraries are available at the USUHS, WRAIR, WRAMC, NNMC, NIH, and National Library of Medicine (NLM). In addition, many medical journals are now available as full text through our on-line internet services.

III. Fellow Expectations

A. Approval Requirement

It is the Fellow's responsibility to notify and seek approval of the Director(s) of the program before engaging in any "optional" courses, rotations, and projects. If the Fellow is broached about engaging in a project, he/she must indicate to the individual that they must first seek approval before agreeing to participate. Furthermore, in addition to the semi-annual and annual evaluation that will occur throughout the Fellowship program (covered under section K of the handbook), Fellows will be required to meet with the Director(s) quarterly if requested to discuss the course of the studies.

B. Required Courses, Locations, and Times

While the Program offers an array of “optional” courses that can be taken with pre-approval from the Director(s), the Fellow must complete the listed course requirements in order to fulfill the Fellowship requirements. To review these required courses, please refer to the appendix entitled Course Work Information. For inclusion in the credentials file, WRAIR Fellow’s must provide a copy of their certificate of completion for each of the listed courses to the Clinical Pharmacology Educational Specialist at WRAIR. In addition, USUHS Fellow’s must provide a copy of their certificate of completion for each of the listed courses to the administrative assistant at USUHS.

It is also recommended to the Fellow, that if they partake in any extra training whether through personal choice or mandated by the Army, they submit their certificate to the Educational Specialist at WRAIR for inclusion into their file.

**Note: Please be sure to confirm the dates and times with the appropriate office or web site to ensure this information is current.*

C. FDA Rotation

The FDA Rotation furnishes a very special, one-of-a-kind training privilege for Fellows. Coupled with hands-on experience in “learning trials” and nonclinical toxicology and pharmacology, this fellowship is as complete a postdoctoral training in drug development and regulatory science as exists anywhere. The FDA rotation provides an understanding of the regulatory aspects of drug development, and an appreciation for the FDA’s perspective as protectors of public safety and how important it is to the clinical pharmacologists’ role in drug development. An approximately 3-4 month rotation is designed to immerse you in the regulatory environment. The rotation should occur during the second training year, generally in the second semester. During this time, the FDA provides an excellent course on clinical trial design (refer to appendix entitled Course Work Information for more details, title of the course: Topics in Clinical Trials), which Fellows are to attend while there. Fellows may setup a rotation in any division of the FDA (usually one of the divisions of CDER: Center for Drug evaluation and Research). Fellows should discuss their ideas for this experience with the Program Directors in the Fall and begin making arrangements no later than August-September of their second year. The Program faculty can assist in making contacts for a mentor.

**Note: For information on how to set up an FDA rotation and for training objectives, please refer to the appendix entitled FDA.*

D. Clinical Pharmacology Unit Rotation

Every Fellow must obtain experience in conducting clinical (human) drug research. If the Fellow’s selected research project is a clinical study, the requirement for this rotation may be satisfied by the clinical research project. This needs to be approved by the Program Directors. Prerequisites for this Rotation include the Good Clinical Practices, Human Participant Protections, and ethics courses (refer to appendix entitled Course Work Information for more details). Activities will include: reading the protocol; consent and case report forms; participating in the screening of potential research subjects and the volunteer study visits; drug accountability; drug concentration analysis (analytical laboratory); data collection; evaluation of potential

adverse events; and reading a clinical study report. Based upon the Fellows activities and the availability within the unit to accept an incoming Fellow, this course requirement is usually completed early on initially and then in the mid-part of the second year. Prerequisite courses must be completed. It is highly desirable for the Fellow to complete at least two rotations if the Fellow does not already have extensive clinical trials experience. The rotation can be completed at the USUHS outpatient clinical research unit or the WRAIR Clinical Trials outpatient unit. Objectives to be completed during this rotation are in the appendix entitled Additional Required Rotations (or Required Rotations).

E. Research Project Milestones & Dates

Successful completion of a major research project is one of the key requirements for graduation from the Fellowship Training Program. The Fellow may pursue a research project of interest to himself/herself as long as it can be supported via existing research programs, a strong mentor is available, it is relevant to clinical pharmacology, and it is approved by the Program Directors. Projects that directly support the WRAIR drug development critical path are strongly encouraged for Army Fellows. Once the Fellow arrives, 2 to 3 possible critical path projects may be identified by staff for the Fellow to consider. Translational medicine projects that are not in the Fellow's area of expertise and will likely be in a future job description are encouraged. A clinical trial, if the Fellow does not already have experience with clinical trials, is highly desirable for physician Fellows. A second project should also be pursued in case the first project does not succeed.

It is projected that in the first 3 to 4 months, the Fellow will meet with staff members at the WRAIR, USUHS, and FDA to explore the various ongoing R&D projects. Once the Fellow identifies a potential project and has received a commitment from the potential mentor indicating that he/she will be able to guide, advise, and supervise the Fellow, the Fellow should outline the project for the Program Directors to obtain written approval. This should be done using the Fellow Research Project Approval Form (see appendix entitled Research Project Information).

If approved, the Fellow will present the research proposal (a 30-45 minute oral presentation followed by 10-20 minutes of discussion/critique) to the faculty, other Fellows, and other invited individuals from the surrounding institutions. This normally takes place in the winter (typically December) of the first training year. Following the presentation, the Fellow may need to conduct additional background reading, as modifications to the plan may be required. Following completion of the research, the Fellow will present a final oral presentation to the faculty, other Fellows, and invited individuals on the results and conclusions of the project. The final oral presentation normally occurs in the winter/spring of the second year (typically in May or June).

The Fellow will prepare a written manuscript suitable for publication in a peer-reviewed journal. The Fellow should be the first author of this publication, so this needs to be established with the mentor at the onset of the research project. If more than one publication results from the Fellow's research, the Fellow need not be the first author on all publications. All manuscripts and abstracts must include the required disclaimer (check current wording) and have clearance through the WRAIR Public Affairs Office per USAMRMC Regulation 360-1 (please refer to appendix entitled Research Project Information for more clarification). This is currently accomplished using MATS (Manuscript and Abstract Tracking System). The manuscript should be submitted for publication before graduation, ideally by the end of March.

**Note: It is expected that the Fellow's mentor be in attendance at both oral presentations.*

F. Scientific Committee Experience

Army Fellows are expected to attend regularly and substantially contribute to a preclinical and clinical development team meeting. Contribution to WRAIR's drug development critical path is an objective of this training program. Following graduation, Fellows will likely be leading such teams.

G. IRB/HURC and P&T Committee Experience

Fellows are expected to participate in or observe the Institutional Review Board (IRB)/Human Use Review (HURC) as well as the combined WRAMC/NNMC Pharmacy and Therapeutics (P&T) committee. Following graduation, Fellows may serve on these committees.

H. Teaching Experience

Fellows are expected to acquire experience with teaching, which is gained through interactions with the house-staff and assisting in teaching the 3rd and 4th year medical students clinical pharmacology course at USUHS. Non-physician Fellows will be paired each year with a Physician Fellow/staff member. In the second year, it is expected that the non-physician Fellow will prepare the small group discussions under the tutelage of the staff member (please refer to the appendix entitled Course Work Information).

I. Clinical Consultation Service

The Fellows are expected to be on-call for monthly rotations on the Clinical Pharmacology Clinical Consultation Service. Physician and non-Physician Fellows will be paired together each month while on call and will be expected to attend morning report together during their rotation. Morning report is typically on Mondays and Fridays at the NNMC. The schedule should be prepared by the second year Fellows at the beginning of each year, approved by the Program Directors, and be provided to the USUHS and WRAIR administrative assistants. It is the responsibility of the Fellows to coordinate any changes to the call schedule, and keep the administrative assistants notified of any changes.

For any consultations the Fellow pairing sees with Clinical Pharmacology Staff or discuss in the Morning Report setting, they will present it at the monthly Division of Clinical Pharmacology/Medical Toxicology Educational Consultation Conference with an in depth analysis and discussion. A minimum of four formal consults are required for write up and conference presentation per four week rotation, or in the case of physician Fellows, a minimum of at least ten consults per year of the fellowship.

**Note: For information on the Consult Service and the Educational Consultation Conference, please refer to the appendix entitled Additional Required Rotations (or Required Rotations).*

J. Clinical Pharmacology Lecture Series

The Program sponsors a regular (weekly) clinical pharmacology lecture series, where in-house faculty and Fellows, as well as invited speakers, give presentations. Fellows will use this opportunity to present their approved research proposal, during their first year, as well as the results of their research project near the end of the second year. The Fellow's peers, the Fellow's mentor, other faculty, and invited guests will provide constructive critique of the science and

presentation skills of the Fellow. Additional presentations include core clinical pharmacology and related topics.

The responsibility for introducing the lectures will be divided among the first year Fellows at the beginning of the academic year; in addition, Fellows may be required to help the Educational Specialist in inviting and scheduling the Lecture Series. Before inviting/scheduling lecturers, the Educational Specialist (and potentially the Fellows) will be required to secure approval from the Program Director(s). Details regarding the month's speakers, topics, location, dates, and times should be sent, via email, to the clinical pharmacology lecture distribution list well in advance of each month's talks. This ongoing networking will provide the Fellow with valuable contacts in the clinical pharmacology community, as well as a better insight into the research and activities being conducted at other institutions, and will identify future potential collaborators.

Under the supervision of a faculty member, some of the scheduled lectures will be conducted as a journal club, where the Fellows will present important articles in clinical pharmacology and learn to critically evaluate a research paper. If needed, journal clubs will be scheduled around the time of the lecture series. Each Fellow must lead journal club at least once in each year of their fellowship (*Please refer to the appendix entitled Lecture Series Information for more information*).

K. Clinical Skills for Fellows Participating in GME

The physician Fellow is expected to maintain their medical credentials, including medical licensing, primary board certification/re-certification, and hospital (WRAMC and NNMC) privileges and credentials. It is recommended that the physician Fellow see patients a ½ day per week during their Fellowship Training Program and keep hospital privileges in their primary MOS.

L. Additional Rotations

Fellows are expected to do a 2-4 week rotation at the Army Pharmacovigilance Center learning to do passive and directed surveillance.

In addition, Fellows will spend one day per week for one month at the National Capital Area Poison Control Center, located in Washington DC, to learn more about the management of routine and complicated poisonings.

**Note: Please refer to the appendix entitled Course Work Information and Additional Required Rotations (or Required Rotations) for more information*

M. Additional Educational Opportunities

Every Fellow must spend time learning modern drug analysis (e.g. mass spectrometry). This is now offered in an educational series at WRAIR. The Fellows should monitor the FDA Meetings (<http://www.fda.gov/opacom/hpmeetings.html>) to take advantage of appropriate offerings. They will provide all staff a monthly update while on call. Additional relevant training is also encouraged. Funding and attendance must be approved in advance since there is limited funding for these optional offerings. (*Please refer to the appendix entitled Course Work Information for more details*)

N. Clinical Pharmacology Board Certification

The Fellow is expected to meet all eligibility requirements to sit for the American Board of Clinical Pharmacology (ABCP) examination. Fellows are expected to take and pass the Boards after completing the fellowship by developing the necessary fund of knowledge. The ABCP examination is administered every two years in October. The deadline for application is usually in March or April. The requirements can be found at www.abcp.net.

Once Fellows pass the ABCP Examination, the Fellows will be Diplomates of the American Board of Clinical Pharmacology.

O. Evaluation Procedures and Criteria

Fellows will be evaluated every six months during the Fellowship. The Fellow will maintain a cumulative log (entitled: Clinical Pharmacology Fellow Activity Log) of their activities and present copies to the faculty prior to their evaluations (see appendix entitled Course Work Information). The following are areas that will be evaluated (see appendix entitled Evaluations):

- Participation in all scheduled events
- Successful and timely completion with documentation of all Fellowship requirements
- Knowledge of clinical pharmacology, drug development, and clinical research
- Showing respect and compassion for the patients and research volunteers
- Interpersonal, written, and oral communication skills needed to function as a clinical pharmacologist
- Demonstration of professionalism, respect for colleagues, and the ability to resolve any issues in a mature manner
- The ability to formulate a research problem, obtain relevant background information, develop a logical and scientifically sound plan for investigation, efficiently execute the research plan, correctly interpret the data, draw correct conclusions, identify any weaknesses in the methods used, and plan follow-on studies.

Should there be any areas where improvement by a Fellow is necessary, the faculty will provide suggestions and direction for improving performance. Should an issue not be resolved at the program level, the Fellow or faculty may address it with the WRAIR General Medical Education Committee (GMEC) or the USUHS Department of Medicine's Education Committee.

The Fellows will in turn provide feedback and an evaluation of the Program and faculty (see appendix entitled Evaluations for an example of the form).

P. Training Records

Maintenance of the training records will be done by the Division of Clinical Pharmacology and Medical Toxicology (USUHS) for all civilian Fellows and the Division of Experimental Therapeutics, Department of Clinical Pharmacology and Translational Medicine (WRAIR) for all military Fellows. It is the Fellow's responsibility to ensure that all required materials are submitted in their files. These records will include copies of medical licenses, primary board certification, certificates of all completed courses, protocols authored, oral presentations given in

the Program, abstracts and oral presentations submitted for presentation at professional meetings, and published papers.

IV. Professional Meeting Attendance & Presentation

Fellows will be funded to attend the annual meetings of the American Society of Clinical Pharmacology and Therapeutics (ASCPT). Army Fellows will also be funded to attend the American Society of Tropical Medicine and Hygiene (ASTMH). The ASCPT meeting is usually held in March or April, and the abstract submission deadline is typically in September. The ASTMH meeting is usually held in November or December, and the abstract submission deadline is typically in May.

The Fellow is expected to present his/her research at a national or international conference, ideally a clinical pharmacology conference if possible (e.g. ASCPT). If the ASCPT is not possible, practical, or optimal, the other alternative would typically be for the Fellow to present at the ASTMH.

All leave/vacation and passes should be approved by the designated Director (i.e. WRAIR Fellows will be approved by the WRAIR Director and the USUHS Fellows will be approved by the USUHS Director).

V. Graduation

Upon successful completion of all Fellowship requirements, the Fellow will be presented with a certificate attesting to same. Army Fellows will participate in the annual WRAIR graduation ceremony, held jointly with the WRAIR Preventive Medicine residency and the WRAIR Laboratory Animal Medicine residency. The Graduation ceremony is usually held in the latter part of June.

MEMORANDUM FOR The Clinical Pharmacology Fellowship Training Program

SUBJECT: Policy on Due Process for Participants in Professional Education and Training Program

1. GENERAL.

a. This document outlines the process of management at the Walter Reed Army Institute of Research (WRAIR) for Fellows who are accepted through a formal board selection process and encounter academic, technical, and/or professional conduct problems. The procedures prescribed herein apply to program level remediation, probation, extension of training, and termination from training. These procedures present a sequence of corrective action emphasizing due process, thorough documentation of all actions, and timeliness of the process.

b. These procedures must be applied uniformly and fairly to all Fellows and Faculty in each program. Institutional policies apply to all Fellows in its training programs for issues relating to professional or academic performance, regardless of the sponsoring Service. Issues of misconduct or noncompliance with Service regulations, unrelated to academic or professional performance, must be managed according to the policies of the Fellow's sponsoring Service.

c. Upon entry into a training program, Fellows will be provided a copy of this Due Process Policy and Procedures document. The Fellow will sign a statement acknowledging receipt and review of such documents as well as understanding their content. This signed statement will be maintained in the Fellow's training file.

d. A Fellow's refusal to acknowledge receipt during any process prescribed herein will not result in a delay of the action or proceeding.

2. DEFINITION OF TERMS. These terms are defined to conform to the administrative and Command structures at WRAIR.

a. Director of Medical Education (DME). An institutional official having the authority and the responsibility for oversight and administration of Graduate Medical Education (GME) programs and Long Term Health Education Training Programs (LTHET). The official responsible for GME/LTHET programs at WRAIR is the Deputy Commander.

b. Decision Authority. An individual designated in institutional documents as having initial authority for probation or termination. The Decision Authority at WRAIR is appointed by the Deputy Commander or Commander. The current Decision Authority

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can be determined by contacting the Office of the Deputy Commander. The Decision Authority may appoint a designee to carry out his/her duties in their absence.

c. Appellate Authority. An individual designated in institutional documents as having final authority for probation or termination. The appellate authority at WRAIR is the Commander.

d. Graduate Medical Education Committee (GMEC). The institutional committee composed of the DME, Program Director(s), and at least one Fellow representative whose charter is to monitor and advise on all aspects of GME/LTHET in the institution. All GMEC members, including the Fellow, are voting members when hearings related to adverse actions are conducted.

e. Institutional Document. The organizational documents that define the structure and the chain of authority and accountability for the institution sponsoring GME/LTHET.

f. Remedial Action. Program level remediation, probation, extension and/or termination from training are considered remedial actions.

g. Adverse Actions. Probation or terminations from training are considered adverse actions.

3. RESPONSIBILITY. Program Directors must assess for deficiencies in knowledge, skills, and attitudes regarding military officership, including failure to comply with military regulations such as those prescribing weight, physical fitness, licensure or other requirements. Program Directors are responsible for compliance with the requirements prescribed herein.

a. Fellows must be provided written performance evaluations at appropriate intervals. Frequency of evaluations must satisfy program requirements published by the American Board of Clinical Pharmacology, Inc. and should be performed at least semi-annually.

b. A training file must be maintained for each Fellow.

c. A training agreement must be maintained for each Fellow. This agreement must be signed by the Fellow prior to entry into GME/LTHET and maintained in the Fellow's training file.

d. Remedial action must be instituted when a Program Director identifies a Fellow with significant deficiencies in knowledge, skills, or professional attitudes.

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e. The Program Director will immediately investigate any allegation of substandard academic or unprofessional performance. If during an interview an individual begins to disclose information that indicates a violation of the Uniform Code of Military Justice (UCMJ) may have occurred, the Program Director will halt the interview immediately, apprise the individual of his/her rights against self incrimination and immediately contact the proper legal and law enforcement channels. If the individual discloses information the Program Director determines may be a violation of the UCMJ, the incident must be presented to the DME for consideration of adverse action. Any adverse action must afford due process in accordance with this document.

4. **DOCUMENTATION.** All remedial actions must be based upon thorough written documentation. This begins with initial counseling followed by written performance evaluations and periodic statements by the Program Director concerning the success of the Fellow in achieving designated milestones in professional development.

a. Assessment of the Fellow's performance should consider the progressive development under supervision of the knowledge, skills, and attitudes required for safe, effective and compassionate patient care commensurate with the Fellow's level of advancement and responsibility.

b. When progress is below expectations, the Program Director must assess:

(1) The adequacy of training experience.

(2) The adequacy of supervision.

(3) The adequacy of the Fellow's personal learning program for professional growth with guidance from the teaching staff.

(4) The Fellow's full participation in the educational and scholarly activities of the program.

5. **REMEDIAL ACTION.** There must be a written plan for any remedial action. It must include objective criteria by which improvement can be judged. Fellows may be considered for program level remediation, probation, extension and/or termination from training based upon any of the following:

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- a. Failure to meet academic or technical performance standards or objectives of the training program.
- b. Lack of application, to include but not limited to absences, tardiness, and/or failure to perform fellowship duties in a timely or adequate fashion.
- c. Conduct considered unprofessional by the Program Director that directly affects the practice of medicine, research, or the course of training.
- d. Failure to meet professional or administrative responsibilities, such as those prescribing weight, physical fitness, licensure or other requirements.
- e. An incident of gross negligence or willful misconduct, including a violation of the UCMJ.
- f. Two-time nonselect for promotion

6. PROGRAM LEVEL REMEDIATION. This action allows for correction of deficiencies without probation. The DME must be informed of this action in writing by the Program Director prior to initiating this action; however, it is not considered to be adverse. Such remediation may not exceed 60 days nor be extended or repeated. This level of remediation must precede placement of the Fellow on probation except in cases of gross negligence or willful misconduct as judged by the Program Director. Fellows alleged to have committed such acts of gross negligence or willful misconduct will be referred to the DME for immediate summary action.

- a. The Program Director will identify Fellows whose academic or professional performance fails to meet expected standards of knowledge, skills, or attitudes.
- b. The Program Director will provide the Fellow with clear written documentation including the following points:
 - (1) A description of specific deficiencies in performance.
 - (2) The methods to use to improve the noted deficiencies.
 - (3) A list of objective measures which must be achieved to be removed from remediation.
 - (4) Any restrictions or conditions placed on the Fellow during remediation.

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(5) A time frame for documentation of improvement not to exceed 60 days.

c. The Program Director will ensure that the Fellow understands the deficiencies as well as requirements for improvement and offer counseling and assistance to help the Fellow.

d. The Program Director may designate an Advisor to assist the Fellow during remediation.

e. The Fellow must sign a statement acknowledging program level remediation. The signed statement will be maintained in the Fellow's training file.

7. **PROBATION.** A Program Director may propose probation after a period of program level remediation or after a single incident of gross negligence or willful misconduct. Probation is a period of supervision initiated to assist the Fellow in understanding and correcting significant specific deficits in knowledge, skills, or attitudes. Probation may be approved, ended, or extended only by recommendation of the GMEC. Probation may end in return to full training status with or without extension of training, withdrawal, or termination.

a. The proposal for probation may be based upon one or more of the following:

(1) Documented failure to meet academic or technical performance standards of the program.

(2) Lack of endeavor in the training program.

(3) Lack of application of the Fellow's knowledge or skill.

(4) Unprofessional conduct (medical and/or military).

(5) Documented failure to correct deficiencies despite counseling.

(6) Documented regression or failure to progress after removal from probation despite counseling.

(7) Disciplinary problems.

(8) Substance abuse (in accordance with applicable Service regulations).

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(9) Failure to obtain or maintain a valid unrestricted state medical license in compliance with Department of Defense regulation (for physician Fellows only).

(10) Failure to maintain compliance with weight or physical fitness requirements.

(11) An incident of gross negligence or willful misconduct, including a violation of the UCMJ.

(12) Other circumstances deemed significant by the Program Director.

b. In order for a Fellow to be placed on probation, the Program Director must notify the Fellow in writing that a proposal for probation is being considered. The notification must include specific reasons for the proposed action and provide the Fellow a minimum of 5 calendar days to submit a written response and meet with the Program Director.

c. The Program Director must then notify the Fellow in writing if the proposal for probation will go forward within 5 calendar days following receipt of the Fellow's response, if submitted. The notification must include specific reasons for the contemplated action and advise the Fellow of their rights (see paragraph 11) for due process under this policy. At this time, the Program Director must provide the Fellow with a copy of the probation request, as it will be submitted to the DME and applicable institutional policy on due process. A record of the notification including a signed acknowledgment of receipt of a copy of the probation request must be maintained in the Fellow's training file.

d. If the Program Director's decision is to request probation, the request must be submitted to the DME immediately after notifying the Fellow of the intent to proceed with a probation request. The request should include the following:

(1) Specific reasons for the proposed probation.

(2) Performance plan which identifies the steps for improvement during probation.

(3) Measurable endpoints for successful completion of the probation.

(4) Recommended duration of probation.

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- (5) The notification to the resident proposing probation.
- (6) The resident's response (if any) to the probation proposal.
- (7) Academic file.
- (8) Documentation of all previous counseling
- (9) Results of program level remediation (if applicable).

e. Upon receipt of the program Director's request for probation, the DME must determine whether to convene a probation hearing and inform the Program Director of the date and time within 2 calendar days. A hearing to address a probation request must be at least 10 working days after the Fellow is notified of the decision to refer the matter for a hearing. GMEC may serve as a probation hearing or a special meeting of the GMEC may be convened to address the probation request.

f. Upon receipt of the DME's decision, the Program Director will notify the Fellow of the decision within 2 calendar days. If the decision is to refer the matter for hearing, the Program Director will also inform the Fellow of the date and time of the hearing and the Fellow's rights (see paragraph 11) regarding the hearing. A copy of the probation request will be made available to members of the GMEC prior to and during the probation hearing.

g. The Fellow is encouraged to request a meeting with the DME prior to the probation hearing in order to clarify any issues concerning the hearing. The Fellow will be given the opportunity to appear before the GMEC. The Fellow must provide the name of any accompanying attorney and witnesses and any supporting documentation for the hearing to the DME at least 2 working days before the date of the hearing. The accompanying attorney may be present solely in an advisory role to the Fellow. The attorney may advise the Fellow, but may not present, cross examine or dispute.

h. The GMEC will consider the request and all relevant information presented at the hearing and renders its recommendation. This is the initial approval authority for placement of Fellows on probation. The decision on the recommendation for probation will be determined by a vote. For the action to go forward, greater than 50% must vote in favor of probation. The deliberations and voting will be in closed session. All but the voting committee members, DME, and recorder must leave the room. The proceedings and recommendations must be mentioned in the minutes of the GMEC, but detailed records of the proceedings and vote will be kept confidentially in the local medical education office. MCMR-UWZ-A

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i. The DME will prepare a summary of the proceedings and recommendation. This summary along with the Program Director's original request and the Fellow's written statements will be forwarded to the Decision Authority within 1 working day following adjournment.

j. The Decision Authority (or his/her designee) must notify the DME of the decision within 2 calendar days following receipt of the summary of the proceedings and recommendation.

k. The DME will notify the Fellow in writing within 2 calendar days of the decision. If the decision is to place the Fellow on probation, the notification will also include the Fellow's right to appeal the decision to the Commander within 5 working days following the date the notification is received by the Fellow. The Fellow must sign and date the notification to acknowledge receipt. A copy of this notification and acknowledgement will be maintained in the Fellow's training file.

l. The Fellow may make a one-time written one page appeal of the probation decision through the Decision Authority to the Commander. The probation request and GMEC minutes must be submitted to the Commander for review.

m. Written notification of the decision regarding an appeal must be provided to the Fellow within 2 working days following receipt of the appeal. The decision is final and there is no right to appeal to the Directorate of Medical Education, MEDCOM, Medical Corps Chief, MS Corps Chief, The Surgeon General, or other authorities.

n. The period of probation will generally be at least 30 days and in all cases will not exceed 90 days. The GMEC may vote to extend the term of probation for a period not to exceed an additional 90 days on recommendation of the Program Director. Fellows who fail to demonstrate adequate improvement after two consecutive periods of probation will generally be recommended for termination under due process procedures by the Program Director.

o. The Program Director will counsel the Fellow on the terms and conditions of the probation. This session must be documented and an acknowledgment signed by the Fellow. The Program Director will assign a faculty advisor to assist the Fellow in the improvement plan.

p. If appropriate, voluntary medical, psychological, or learning disability evaluation will be offered to the Fellow, at no cost to the Fellow during the remediation or probation period. Requests for evaluation outside the institution will be reviewed on a case-by-

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case basis and honored on the basis of the merits of the request. The Fellow will be responsible for all costs associated with outside evaluations.

q. The Program Director will submit a monthly written report to the GMEC regarding the Fellow's performance during probation. A copy of this report will be submitted to the DME and to the probated Fellow no later than 3 calendar days prior to the next scheduled meeting of the GMEC. The Fellow will be requested to sign the report acknowledging its receipt. The Fellow may also submit written statements on his/her behalf to the GMEC.

r. The DME will notify the Directorate of Medical Education, MEDCOM, ATTN: DASG-PSZ-MG, in writing within 5 calendar days following the effective date when any military Fellow is placed on probation. This Directorate will notify the appropriate authority if the military Fellow is from another Service. The MTF or USUHS GME Office must notify the appropriate organization for any civilian Fellow placed on probation in accordance with their training agreements. For LTHET Fellows, removal from the program for medical, disciplinary, or other reasons will be determined by the Department of Health and Education Training (DHET).

8. COMPLETION OF PROBATION. Probation may be ended under several conditions.

a. The Program Director may determine the Fellow's performance has improved and meets the stated terms for successful remediation (all measurable endpoints have been achieved). The Program Director may petition the GMEC to remove the Fellow from probation. A majority vote (greater than fifty per cent of the voting members present) by the GMEC is needed to forward the recommendation to the designated decision making authority.

b. The Fellow may voluntarily resign from the program (see paragraph 13).

c. The Fellow's training is terminated.

9. EXTENSION OF TRAINING. Under ordinary circumstances, brief periods of absence can be accommodated without extension of training, provided that the sum of ordinary leave, passes, convalescent leave, travel time, inprocessing/outprocessing time, and the absence period do not exceed 30 calendar days in an academic year as per Army Regulation 351-3, 6-21 and 10-10. Leave, passes, convalescent leave, travel time, inprocessing/outprocessing time, and other absences are governed by existing regulatory and local guidance. If the recommended probation period exceeds more than one half the elective time normally allocated within the residency curriculum, a request

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for extension may be initiated. In those instances of more prolonged absence, the Program Director may recommend extension of training. Extension of training is not considered an adverse action in and of itself and, therefore, requires no hearing or appeal. Extension of training may or may not involve probation status and may occur for other reasons, such as medical, personal, or administrative. Extensions of training as part of the probation require no hearing or appeal since due process is part of the probation procedure.

a. Any time an extension of training is requested, the Fellow must be notified in writing of the intent to extend training and the reasons for the action. The Fellow must sign the notification acknowledging receipt.

b. A written request for extension with the stated reasons enumerated must be sent to the GMEC. The GMEC may recommend extension of training. This action requires a majority vote (greater than fifty per cent of the voting members present) by the members of the committee and is subject to approval by the Decision Authority. The Fellow must be notified in writing of the decision for extension of training and a copy of the acknowledged receipt must be maintained by the Program Director in the Fellow's training file.

c. Since extension of training may affect future assignments, special pays, and obligations for Army Fellows, the Directorate of Medical Education, MEDCOM, ATTN: DASG-PSZ-MG, must be notified within 5 calendar days of the action for final approval. For LTHET Fellows, they must notify their consultant and their Leader Development LTHET Program Manager.

10. TERMINATION FROM TRAINING. Termination is the most serious action that can be proposed by a Program Director. Termination will normally be imposed only after a period of formal probation, two-time non-select for promotion, or after a single incident of gross negligence or willful misconduct. A recommendation for termination must be approved by a two-thirds vote of the GMEC.

a. A recommendation for termination must be based upon one of the following:

(1) Failure to satisfactorily progress toward correction of deficiencies while on probation.

(2) Regression or failure to satisfactorily progress after removal from probation.

(3) Any act of gross negligence or willful misconduct. This can include a pattern of past performance or a single act. Under these circumstances, the Fellow may be

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placed on administrative duties and removed from patient care responsibilities until resolution of the termination process. Termination under these circumstances requires notification of the appropriate credentialing authority.

(4) Two-time non-select for promotion.

b. In order for a Fellow to be terminated from training, the Program Director must notify the Fellow in writing that termination is being considered. The notification must include specific reasons for the proposed action and provide the Fellow a minimum of 5 calendar days to submit a written response and meet with the Program Director.

c. The Program Director must then notify the Fellow in writing if the proposal for termination will go forward within 5 calendar days following receipt of the Fellow's response, if submitted. The notification must include specific reasons for the contemplated action and advise the Fellow of their rights (see paragraph 11) for due process under this policy. At this time, the Program Director must provide the Fellow with a copy of the termination request as it will be submitted to the DME and applicable institutional policy on due process. A record of the notification including a signed acknowledgment of receipt of a copy of the termination request must be maintained in the Fellow's training file.

d. If the Program Director's decision is to request termination, the request must be submitted to the DME immediately after notifying the Fellow of the intent to proceed with a termination request. The request should include the following:

- (1) Specific reasons for the proposed termination.
- (2) A copy of the probation request, if applicable.
- (3) The notification to the Fellow proposing termination.
- (4) The Fellow's response (if any) to the termination proposal.
- (5) Academic file.
- (6) Documentation of all previous counseling.
- (7) Results of prior remediation or probation periods.

e. Upon receipt of the Program Director's request for termination, the DME must determine whether to convene a termination hearing and inform the Program Director of

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the date and time within 2 calendar days. A hearing to address a termination request must be at least 10 working days after the Fellow is notified of the decision to refer the matter for a hearing. The regularly scheduled meeting of the GMEC may serve as a termination hearing or a special meeting of the GMEC may be convened to address the termination request.

f. Upon receipt of the DME's decision, the Program Director will notify the Fellow of the decision within 2 calendar days. If the decision is to refer the matter for a hearing, the Program Director will also inform the Fellow of the date and time of the hearing and the Fellow's rights (see paragraph 11) regarding the hearing. A copy of the termination request will be made available to members of the GMEC prior to and during the termination hearing.

g. The Fellow is encouraged to request a meeting with the DME prior to the termination hearing in order to clarify any issues concerning the hearing. The Fellow will be given the opportunity to appear before the GMEC. The Fellow must provide the name of any accompanying attorney and witnesses and any supporting documentation for the hearing to the DME at least 2 working days before the date of the hearing.

h. The GMEC will consider the request and all relevant information received at the hearing and renders its recommendation. This is the initial approval authority for termination from training. The decision on the recommendation for termination will be determined by a vote. For the action to go forward, greater than two-thirds must vote in favor of termination. The deliberations and voting will be in closed session. All but the voting committee members, DME, and recorder must leave the room. The proceedings and recommendations must be mentioned in the minutes of the GMEC, but detailed records of the proceedings and vote will be kept confidentially in the local medical education office.

i. The DME will prepare a summary of the proceedings and recommendation. This summary along with the Program Director's original request and the Fellow's written statements will be forwarded to the Decision Authority within 1 working day following adjournment.

j. The Decision Authority must notify the DME of the decision within 2 calendar days following receipt of the summary of proceedings and recommendation.

k. The DME will notify the Fellow in writing within 2 calendar days of the decision. If the decision is to terminate the Fellow from training, the notification will also include the Fellow's right to appeal the decision to the Commander within 5 working days following the date the notification is received by the Fellow. The Fellow must sign and

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date the notification to acknowledge receipt. A copy of this notification and acknowledgement will be maintained in the Fellow's training file.

l. The Fellow may make a one-time submission of an appeal of the termination decision through the Decision Authority to the Commander following a hearing if termination is approved. The appeal must be filed within 1 week of the decision being received in writing by the Fellow. The termination request and GMEC minutes must be submitted to the Commander for review.

m. Written notification of the decision regarding an appeal must be provided to the Fellow within 2 working days following receipt of the appeal. The decision is final and there is no right to appeal to the Directorate of Medical Education, MEDCOM, Medical Corps Chief, MS Corps Chief, The Surgeon General, or other authorities.

n. The DME will notify the Directorate of Medical Education, MEDCOM, ATTN: DASG-PSZ-MG, in writing within 5 calendar days following the decision to terminate any military Fellow. This Directorate will notify the appropriate authority if the military Fellow is from another Service. The MTF GME office must notify the appropriate organization for any civilian Fellow terminated in accordance with their training agreements.

11. FELLOW'S RIGHTS UNDER DUE PROCESS AND CONDUCT OF GMEC HEARINGS ON PROBATION OR TERMINATION. The proceedings of the GMEC are administrative and are not bound by formal rules of evidence or strict procedural format. Records of the proceedings will be kept by the DME for at least five years.

a. At least seventy-five percent of the official membership must be present for hearings on probation or termination. At least one Fellow representative must be present.

b. If the Fellow asks to be present at the hearing but cannot attend the hearing as scheduled, a reasonable attempt should be made to reschedule the meeting without causing undue delay in the proceedings. If this is not possible, the GMEC may proceed in the absence of the Fellow after formally documenting the circumstances and the necessity of proceeding in a timely manner.

c. The Fellow has the following rights in the proceedings:

(1) The right to waive the hearing.

(2) The right to hear the reasons for action as put forth by the Program Director.

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(3) The right to review all documents before the committee.

(4) The right to secure a military legal assistance attorney, or a civilian attorney at the Fellow's expense. The attorney may not ask questions or make arguments, but the Fellow may consult the attorney; however, such consultation may not unduly delay the progress of the proceedings, as judged by the GMEC Chair present at the proceedings.

(5) The right to respond orally and/or in writing to the statements of the Program Director.

(6) The right to request witnesses to speak on his/her behalf or to submit statements from those witnesses. This request will normally be honored; however, the hearing will not be unreasonably delayed in order to allow their appearance. The witnesses may speak on behalf of the Fellow but may not question members of the GMEC. The Chair of the committee may limit time allotted for individual comments.

(7) The right to submit statements or written documents on their own behalf and in support of his/her position, or other information to show why other disposition should occur.

(8) The right to appeal a decision.

c. The GMEC has the responsibility to ensure the concerns of the Program Director meet reasonable criteria for the proposed action. The members of the committee will be encouraged to question the Program Director to clarify any items to ensure that reasonable criteria are being met.

d. The Fellow and any accompanying attorney may be present during the presentation by the Program Director and other witnesses. The Fellow may then make any statements to the committee. The Fellow and the attorney will be excused prior to the deliberations and vote.

12. ADMINISTRATIVE OR JUDICIAL ACTION. If administrative or judicial action is initiated against a Fellow, the DME will evaluate available information to determine if a restriction, suspension, or termination action under this section is warranted. The Directorate of Medical Education, MEDCOM, ATTN: DASG-PSZ-MG, must be notified within 5 calendar days after administrative or judicial action is initiated and when it is completed.

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13. FELLOW RESIGNATION.

a. Fellows may submit a written request to the Program Director resigning from the training program. The resignation request will acknowledge that by resigning from training, the Fellow is making him/herself available for immediate reassignment orders to meet the military's needs.


b. The request will be forwarded to the DME with the Program Director's recommendation, a description of the circumstances of the resignation, and whether or not progress has been satisfactory up until the time of resignation. The Program Director will indicate the number of months of training that have been successfully completed and whether the Fellow will be recommended for future GME/LTHET. The Fellow must review the statement by the Program Director and sign to acknowledge the review.

c. The DME will review the case and recommend approval or disapproval to the designated decision making authority for the institution that will make the final determination.

d. The Directorate of Medical Education, MEDCOM, ATTN: DASG-PSZ-MG, must be notified within 5 calendar days following receipt of all military resignations and the effective date of the resignation. This office will notify MC/MS Branch, PERSCOM, that the physician/non-physician is available for assignment. Non-Army trainees must follow their Service requirements.

14. RE-ENTRY INTO GME/LTHET. Once a Fellow leaves a GME/LTHET training program for any reason (graduation, termination, resignation) there is no option for reinstatement. The physician/non-physician may only pursue further GME/LTHET through application and selection by a designated GME/LTHET selection board. Applicants must meet all current eligibility requirements when submitting an application.

FOR THE COMMANDER:



DONALD G. HEPPNER
COL, US Army, MC
Director of Medical Education

Schools

Professional Education and Training Programs of the Army Medical Department

Headquarters
Department of the Army
Washington, DC
15 October 2007

UNCLASSIFIED

Chapter 6 Medical Corps Policy and Programs

Section I Introduction

6-1. General

This chapter prescribes procedures for applying for all programs of GME whether taken in Federal or civilian medical facilities or colleges and universities. It also provides administrative and control guidance for GME training.

6-2. Policies

The following policies pertaining to education and training apply within the MC:

a. Military professional training sequence. The general sequence for military professional training is discussed below.

(1) *The AMEDD OBLC.* All AC MC officers will attend the OBLC before their first AD assignment in a non-GME status. All RC MC officers will attend OBLC within 3 years of commissioning.

(2) *Combat Casualty Care Course (C4).* Except for those who have attended equivalent training, attendance at the C4 course is required for trainees under the military unique requirement. It is recommended for all career status MC officers between their second and eleventh year of AFCS.

(3) *The CCC.* MC officers in career status will normally attend the resident AMEDD CCC between their fourth to seventh year of AFCS. MC officers participating in GME training will not be released to attend CCC except under unusual circumstances and must be approved by HQDA, OTSG ATTN: DASG-PSZ-MG.

(4) *The MEL 4 equivalent course.* Officers will be considered for attendance at the resident course when they have attained the grade of major or captain promotable (P) between their fifth and eleventh years of AFCS. Because of the limited number of quotas available for resident attendance, MC officers are encouraged to enroll in the nonresident correspondence course of instruction or USAR course. To be eligible for the nonresident course, officers must have completed the CCC and have between 8 and 18 years of AFCS. Waivers may be granted by the commandant, MEL 4 equivalent course, for AFCS.

(5) *The SSC.* All eligible MC officers will be considered for SSC attendance. Eligibility consists of grade of lieutenant colonel or colonel and AFCS between 11–22 years. Officers on the SSC (AWC) OML are encouraged to apply for the AWCDEP.

b. Utilization tours for training. A tour of duty using skills and knowledge developed by significant training experiences will normally occur immediately following the training. The major exception to this general policy is that utilization tours following the CCC and C4 are not required.

c. Methods of assessing needs. Education and training opportunities within the MC, other than GME, are generated by need as assessed by the following methods:

(1) Long-course needs are determined by validated requirements, procurement standards, and recognized requirements.

(2) Short-course needs are determined by a series of annual needs assessments using input from the field, MC specialty consultants, and the MC branch.

d. Training selections. Long-term training selections, other than GME, are made through a formal board process convened by the director, OPMD, AHRC, for degree programs and the chief, MC branch for non-degree programs. Attendance at short courses is approved within the MC branch, AHRC.

e. Constructive credit. MC officers can apply for constructive credit for military courses under AR 350-1 based on experience and other training. Approval of constructive credit is limited because of opportunities available for MC officers to attend the resident CCC and enroll in the nonresident MEL 4 Equivalent Course. Constructive credit is awarded through a formal board process convened by the Commander, AHRC.

6-3. Types of training

a. Military first year graduate medical education (FYGME). This is defined as the first postgraduate year (postgraduate year one (PGY-1)) of accredited training immediately following medical school. The FYGME programs are established in designated hospitals as directed by TSG. The FYGME program will be conducted to meet military requirements and educational standards of the Accreditation Council for Graduate Medical Education (ACGME).

b. Military residencies. Residencies are defined as a formal program of medical specialty training that includes the second and subsequent postgraduate years (postgraduate year two (PGY-2) or above) of accredited training. Completion of training leads to eligibility for certification by an American Board of Medical Specialties. Residencies will be established in designated Army hospitals as directed by TSG. These residencies will be conducted to meet military requirements and educational standards of the ACGME as defined in "Essentials of Accredited Residencies in GME" in order to satisfy requirements for board certification.

c. Chief residents. Where more than one resident is assigned to serve in the last year of clinical training, a chief

resident may be appointed to assume executive responsibility for supervision. This duty may be rotated among the senior residents.

d. Pre-specialty training. Training in certain specialties may require completion of prerequisite training in a separate program. Hospitals conducting this prerequisite will ensure that training is approved by the appropriate specialty board as offering satisfactory training in preparation for specialty board eligibility.

e. Civilian residencies. Residencies in civilian hospitals in various specialties may be made available and used as needed.

f. Fellowships. Fellowships are defined as a formal program of medical subspecialty training following completion of primary specialty training. TSG will approve selected officers as needed for training at military and civilian hospitals in any specialty or research area necessary to the medical mission.

6-4. Training spaces

The Surgeon General will annually approve through an official school year plan the number and location of all specialty training positions available for MC officers. This will consider training capacity at each hospital and Army requirements.

6-5. Applications, appointments, advancements, service agreements, and selections

a. General. All GME applicants must meet prerequisites and all other requirements as prescribed annually under an applicable GME guidance issued by TSG for selection in the training year. However, all applicants must be United States citizens. Active duty applicants must be MC officers. The only means available for an Army AD officer or a civilian to apply for and participate in GME training (PGY2 year and above) is through a Web-based application. Contact the program manager for additional information. Deadline date for application is 15 September of each year. Civilian applicants meet requirements as prescribed under the applicable GME guidance. All GME applications will be submitted as prescribed in the applicable GME guidance. Appointments of medical officers into residency or fellowship training programs will be for the period of time needed to achieve eligibility for an American specialty board. When no specialty board exists, training periods will be determined by TSG. A GME training year (includes the FYGME program) will consist of at least 48 weeks. Medical officers appointed to GME programs having research requirements remain in a training status assigned to the primary training program for the duration of the research period, regardless of the location of the research experience. Research periods performed at other than the primary training program site will not require funding or a permanent change of duty station.

b. Requirements. All Army obligated military medical students, including Reserve Officers' Training Corps (ROTC), Armed Forces Health Professions Scholarship Program (HPSP) and USUHS, are required to apply for the Army FYGME program (PGY-1 year of training). Applicants (military and civilian) must comply with requirements as indicated in the applicable annual FYGME letter of instruction (LOI).

c. Prerequisites for FYGME. Applicants requesting FYGME training must meet, as a minimum, the eligibility requirements, to include security requirements for appointment in the MC USAR (see AR 135-101) and meet the following special eligibility requirements:

- (1) Be a United States citizen.
- (2) Be enrolled full-time in the senior year of a medical degree program in an accredited educational institution in the United States or Puerto Rico. The educational program must be accredited by the appropriate accrediting organization recognized by the Army.
- (3) Meet other eligibility criteria and the established deadline dates as stated in the FYGME LOI available on the Web site.

d. Categories of training. The Army offers GME training in military programs and sponsored and non-sponsored civilian programs. The specialty, start date, and number of positions offered within each Category are published in an annual GME procedural guidance. Sponsored civilian trainees remain on AD and receive full pay and allowances.

e. Non-funded Graduate Medical Education Program (NGMEP). The NGMEP provides an opportunity for AD physicians to be released from AD in order to complete GME training at no expense to the Government in exchange for an agreement to return to AD upon completion, termination, or resignation from training. Applications for the NGMEP will be submitted in the same manner as all other GME applications. If available, training spaces for this program will be approved in the annual GME school year plan.

(1) Eligibility requirements for the NGMEP are as prescribed in the applicable GME guidance. Selectees must disclose any medical condition that would render them ineligible for reentry onto AD under existing requirements. Selected applicants with disqualifying conditions are ineligible for the NGMEP and selection is automatically void.

(2) Upon notification of Army selection, other than Active Army officers must submit a request for release from AD under AR 600-8-24, section VII, chapter 2. Active Army officers must submit an unqualified resignation under AR 600-8-24, section II, chapter 3, including therein a request for appointment in the USAR. A signed NGMEP SA must be submitted with the request for release from AD.

f. Army weight control, Army physical fitness, and licensure. All individuals selected for PGY-2 training and above must comply with AR 600-9 and FM 21-20 as appropriate and licensure requirements as prescribed by applicable law,

DOD, Army and GME guidance. Officers entering a new GME program at the PGY-2 year and above must have passed the APFT within six months "prior to" entering the GME program or have passed the last scheduled APFT, whichever is later. Noncompliance with the Army weight, physical fitness, or license requirements may be a basis for withdrawal of a GME selection or for denial of advancement in GME pursuant to existing policy. The disposition of trainees already in training will be as prescribed under existing guidance governing weight and physical fitness standards and licensure requirements.

g. Advancement of students (PGY-2 year or above). All trainees beginning GME at the PGY-2 or above year of training will be considered for advancement each year until they complete their training as long as specialty educational requirements are met. As a condition of advancement/continuation, the trainee must maintain compliance with prescribed Army and GME policy.

h. SAs and ADSO. All selected applicants must sign a SA for any category of GME training unless the training is covered under a preexisting SA. The ADSO and MTS will be as prescribed in the SA and DOD guidance. The GME training agreement will serve as the document required to extend the AD term of the MC officer as specified in AR 135-215, paragraph 4-2i. Individuals who voluntarily withdraw or are terminated from a GME training program will have an ADSO in accordance with chapter 2.

i. Convening authority.

(1) The JSGMESB is convened annually under the authority of the Assistant Secretary of Defense for Health Affairs (ASD (HA)) and the surgeons general of the U.S. Army, the U.S. Navy, and the U.S. Air Force. Annually, ASD (HA) publishes the rules governing the joint aspects of GME selections. Each surgeon general retains approval authority for the results of their Service's board including assignment of selected applicants from other Services to their Service's teaching programs.

(2) The JSGMESB board membership will consist of individuals as prescribed in the Army memorandum of instruction (MOI) to the selection board. Board members will observe the policies/rules established in the MOI approved each year by the Army SG related to Army selections and rules published by the ASD (HA). The board president of the Army portion of the JSGMESB will be the chief of the MC.

j. Selection results. TSG is the final review and approval authority for all GME selections. All board proceedings are subject to review by the ASD (HA). HQDA, OTSG, ATTN: DASG-PSZ-MG, will release the Army GME results of the JSGMESB.

k. Standby board. If necessary the Army SG will convene a standby board to fill any vacant GME positions. Information concerning available specialties, training locations, deadline date for receipt of applications, and the date of the board will be published by the HQDA, OTSG, ATTN: DASG-PSZ-MG. Selection will be consistent with existing procedural guidance.

l. Selection review board. MC officers selected for GME at the JSGMESB are conditionally selected contingent upon continued satisfactory performance up to the date of entry into GME. Adverse personnel actions and academic difficulties to include the need for imposition of probation and other negative events represent a significant deviation from this satisfactory level of performance. Individuals at institutions (includes appropriate chain of command at non-GME locations) where the selectee is assigned must report adverse actions or decline in performance to HQDA, OTSG, ATTN: DASG-PSZ-MG. As outlined in the provisional selection notification, selection will be re-evaluated by a board appointed by TSG. This board may elect to rescind the selection for entry into a GME program. The Chief, MC is the approval authority for such action.

6-6. Due process

All trainees in GME must be afforded due process as prescribed by policy issued by TSG and as outlined by the ACGME institutional requirements. These policies will be applied uniformly and fairly to all trainees and faculty in all programs. Due process is an institutional methodology through which a trainee is appraised of academic, professional, or behavioral issues which adversely impact the training experience, the proposed interventions, and the measures of success or failure which demonstrate that the identified issues have been rectified. The trainee has the right to respond either writing or person via a formal hearing process. Each institution accredited to conduct GME must develop specific written policies and procedures in accordance with the ACGME institutional requirements and TSG policy compatible with local circumstances. The guidance must address documentation, probation, remediation, termination, training extension, resident resignation, resident's rights, appeals, conduct of GME committee hearings, GME selection, and GME reentry.

6-7. Resident supervision and duty hours

a. Army facilities conducting GME must provide sufficient oversight to ensure that residents are appropriately supervised. Residents must be supervised by teaching staff in such a way that the residents assume progressively increasing responsibility according to education level, ability, and experience. Each institution accredited to conduct GME must develop specific policies and procedures in accordance with: Residency Review Committee (RRC) and ACGME institutional requirements and compatible with local circumstances; standards on resident supervision established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); and supervision policy prescribed by TSG. The guidance must address documentation, privileging of residents, evaluation of residents and

attending physicians, monitoring procedures, and the responsibilities of staff, residents, and institutional governing bodies and authorities.

b. Army facilities conducting GME must ensure that each training program establishes formal written policies governing resident duty hours that foster resident education and facilitate patient care. Duty hours must be consistent with the institutional and program requirements of the specialties and subspecialties that apply to each program. These formal policies must apply to all institutions to which a resident rotates. Off duty employment is strictly prohibited while on AD in a trainee status (to include civilian sponsored residencies and fellowships).

6-8. Military unique curriculum

Each Army MTF engaged in GME must develop and incorporate military unique curricula (MUC) training into GME programs under policy prescribed by ASD (HA) and TSG. Each training facility must include a standardized MUC as part of GME programs. Policy prescribes minimum requirements for training evaluation, documentation, and reporting. Curricula for all GME programs should include aspects of practice unique to the military, including attendance at C4, standardized specialty immaterial PGY-1 curriculum, and military unique curriculum that is standardized and specialty specific for PGY2 and above that includes operational experiences when available, practical and within resource constraints (for example, readiness exercises and participation in short-term deployments and field training exercises). Completion of MUC requirements must be documented and training evaluated. Training plans should include subject matter outlines with the format for instruction as well as lectures, distance learning, and types of operational experiences (for example, field, deployment). The MUC training plan should be reviewed locally at least annually at the time the training report is prepared for submission. Training progress must be reported annually to HQDA, OTSG, ATTN: DASG-PSZ-MG prior to 1 September for consolidation and annual reporting to the ASD (HA) by 30 September of the completed training year.

6-9. Institutional requirements

As stated in ACGME requirements, the purpose of GME is to provide an organized educational program with guidance and supervision of the resident, facilitating the resident's ethical, professional, and personal development while ensuring safe and appropriate care for patients. Training programs must operate under the authority and control of a sponsoring institution. There must be a written statement of institutional commitment to GME that is supported by the governing authority, the administration, and the teaching staff. Sponsoring institutions must be in substantial compliance with the institutional requirements and must ensure that their ACGME accredited programs are in substantial compliance with the program requirements and the applicable institutional requirements. Failure to comply substantially with the institutional requirements may jeopardize the accreditation of all of its sponsored residency programs.

6-10. Applicable publications

Conduct of Army GME programs will conform to provisions described in the following:

- a.* The GME directory (current year, published by the American Medical Association (AMA)).
- b.* AR 40-1.
- c.* Manual of Hospital Accreditation.
- d.* AR 135-101.
- e.* AR 135-100.
- f.* AR 600-9.
- g.* Applicable directives and regulations pertaining to participants in the HPSP, USUHS, and the ROTC Program.
- h.* Applicable GME directives/policies issued by TSG.
- i.* DODD 6000.12.
- j.* DODI 6000.13.
- k.* DODI 6015.24.
- l.* DOD 6025.13-R.

6-11. Location of programs

a. The MTFs authorized to conduct training under this regulation are designated by TSG. These MTFs are listed in the GME directory prepared by the AMA. MTFs so designated will conduct only those FYGME, residency, and fellowship programs that are approved and accredited by the ACGME and by TSG.

b. In addition to training available at Army MTFs, TSG will designate specific GME training programs conducted at civilian institutions that are integrated or affiliated with co-located MTFs. In such designated programs, the following policies exist if the student remains on AD status:

- (1) Sponsored students will be designated as military students for purposes of determining obligation.
- (2) Sponsored students will be assigned to the affiliated MTF.
- (3) The MTF will issue a certificate of training. Such certificate must indicate integration with the civilian institution.

Section II

Administration

6–12. Correspondence

All correspondence concerning GME training programs will be forwarded to HQDA, OTSG, ATTN: DASG–PSZ–MG, Skyline 6, Room 691, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Any correspondence with the AMA, the ACGME, or the American medical specialty boards may be exchanged directly. Information copies must be forwarded to the above address.

6–13. New programs

A request to establish a new training program at an Army MTF must follow OTSG procedures as well as local MTF coordination procedures. Requests are considered annually as part of the school year plan and must be approved by TSG. Information on the policies, timing, and requirements may be obtained from HQDA, OTSG, ATTN: DASG–PSZ–MG.

6–14. Accreditation

Accreditation by the ACGME will be sought and maintained for all Army GME programs. Commanders of AMEDD teaching facilities will program, budget, and fund for accreditation surveys and related expenses of their respective programs in support of this objective. Commanders are responsible for ensuring all programming and funding activities can support any request for program increases before submission of any request to increase the size of GME programs in advance of or during the JSGMESB.

6–15. Program change

Written approval must be obtained from HQDA, OTSG, ATTN: DASG–PSZ–MG, before withdrawal, program change, or completion date change for any student in GME. Local MTF commanders do not require GME approval to switch any student in their FYGME specialty program. However, an information copy of the action will be provided to the above office for accounting purposes. Correspondence from the appropriate medical specialty board (if applicable) indicating board requirements must be included with correspondence forwarded for approval to the above office when a trainee completes GME earlier than the date specified in the training agreement.

6–16. Responsibilities of medical education

The DME is the institutional official having the authority and the responsibility for oversight and administration of GME programs. Each training hospital must designate a physician to serve as DME. The designated individual should have medical education experience, ideally as a PD, as a minimum prerequisite to serve as DME. The individual so designated, along with the MTF commander and the various service chiefs and PDs, will organize; integrate; and supervise the educational program.

6–17. Institutional Graduate Medical Education Committee

a. The ACGME requirements prescribe each training hospital conducting GME must have an organized administrative system to oversee all residency programs. In addition, there must be a designated institutional official who has the authority and the responsibility for the oversight and administration of the GME programs.

b. The Graduate Medical Education Committee (GMEC) is an institutional committee that is responsible for monitoring and advising on all aspects of GME. Each training hospital conducting GME will designate a GMEC. The GMEC will be composed of the DME (accountable institutional official), PDs, and at least one resident representative. The MTF commander may designate other persons as members, but a designated member should not be a GMEC member since he/she is the final reviewing authority. All GMEC members, including the resident, are voting members. All members participate in hearings related to adverse action. The GMEC responsibilities will be as prescribed by ACGME, RRCs, and Army requirements.

6–18. Institutional agreement

a. All institutions conducting GME are responsible for the quality of GME and must retain authority over trainees. Current institutional agreements governing all GME programs are required. Army MTFs sponsoring GME programs will establish and provide trainees with a written hospital training agreement outlining the terms and conditions of the GME appointment. Institutions must also provide trainees with applicable due process, supervision, duty hours, and other policies pertaining to the training experience. The implementation of the terms and conditions must be monitored by the PDs. PDs must ensure residents adhere to established practices, procedures, and policies of the institution. Hospital agreements must conform to ACGME requirements and Army policy.

b. The closure or reduction of a GME program will be in accordance with current DOD guidelines and procedures. Army MTFs must include the following statement in the agreement: “When training programs are directed to close, as may occur due to closure of military institutions or downsizing of training positions, placement of residents in other military or civilian programs is given the highest priority in accordance with the Army and resident’s best interests. It

is preferred that residents complete their training in their current institution if this can be accommodated within the timeframe of the closure. If this is not feasible or not in the best interest of the resident, placement in other military or civilian institutions should be pursued. All residents will be placed so they may complete their GME training with as little disruption as possible. If placed in a civilian institution, military residents will be provided full funding through completion of training.”

c. The hospital training agreement/student contract signed by each student will be maintained by the MTF during the entire period of training.

6-19. Records, clinical statistics, and medical audits

Necessary records and information will be kept in accordance with ACGME requirements and Army policy.

6-20. Certificates

On the individual's completion of GME training or transfer to another MTF to continue training, the appropriate MTF will issue a certificate for the period of training received up to that time. Certificates will be signed by the MTF commander and chief of the specialty or training PD in which training was taken. Certificates for transitional year residencies or similar training will be signed by the MTF commander and the DME or transitional director. Blank DA Forms 3492 are controlled forms and will be issued by HQ HQDA, OTSG, ATTN: DASG-PSZ-MG, DA, to MTFs conducting GME programs. User activities are not required to submit requisitions. GME programs sponsored by Consortia (National Capital Consortium and San Antonio Uniformed Services Health Education Consortium) are authorized to issue approved Consortium certificates instead of the Army specific DA Form 3492 (U.S. Army Medical Department Certificate for Residents, Interns and Fellows). Blank Consortium certificates are distributed through Consortium administrative offices.

6-21. Absence from training

Absence for more than four weeks (physically present for training for less than 48 weeks) of training in one training year may result in an extension of training. All absences must be reviewed by the PD for the reason and or impact on the individual educational experience as well as the program. Trainees must be informed of the effects on their educational program and potential of extension of training or ADSO impact. The institutional GMEC is the local approval authority for such absences. If approved by the GMEC, a request for extension of training outlining the nature of such absences will be submitted to HQDA, OTSG, ATTN: DASG-PSZ-MG, for final approval of adjusted completion date. The request must state a scheduled completion date of GME and a signed statement from the individual indicating their acknowledgment of such extension.

6-22. Plans of instruction

The PD will be responsible for the development of a progressive, comprehensive curriculum. This plan must include all elements as stated in the ACGME program requirements for the specialty and MUC.

6-23. Visiting Professorship Program

The commander of each MTF having one or more residency or fellowship programs will be authorized to invite distinguished United States professional leaders to the MTF as visiting professors. This Visiting Professorship Program is designed to supplement and to enhance the prestige of the AMEDD GME programs. Commanders of MTFs will program, budget, and fund for the TDY for this training in support of their respective GME programs.

6-24. Professional meetings or courses

A commander may authorize trainees to attend meetings in a permissive or regular TDY status only when the training is a necessity or a beneficial part of the GME program. Physicians in the FYGME program will not be granted this authorization. Funds for defraying travel expense and per diem must be funded by the MTF concerned.

Section III Forms

6-25. Evaluation and trainee file

a. An evaluation summary report of a trainee's progression and performance is required for each GME participant. All MTFs conducting GME will maintain written evaluation summary reports. The report will be prepared by the residency PD according to guidelines established by the respective ACGME RRC or other accrediting or certifying agencies. Individual programs will establish evaluation mechanisms and procedures in accordance with specialty requirements and as stated in the GME directory. The DA Form 1970 (House Staff Evaluation Report) may be used, but is not mandatory, as an evaluating document.

b. Trainee evaluation summary reports provide information required for selection, evaluation, and termination of students. DA Form 67-9 is not to be substituted for this purpose.

(1) Trainee evaluations must be performed at least twice annually and a written evaluation summary report must be

prepared each time. The first report is an interim report covering the initial portion of the training year. The second report will be prepared at the completion of the training year.

(2) A final report that summarizes the entire training experience must also be prepared when the trainee completes training and when a trainee departs training for any other reasons. This final report as well as those used in the application for GME or prepared when a trainee resigns or is terminated from training must adhere to the content and format requirements in Army policy.

c. A permanent trainee file is required for each trainee participating in GME. The file must include contracts, rotation and summary evaluations reports, documentation of compliance with MUC requirements, and any other document prescribed by Army policy and the ACGME.

d. A copy of all summary reports will be maintained as a part of the permanent file of the hospital GMEC. A copy of this record will be forwarded to the gaining MTF if the trainee is transferred to another MTF for completion of training. A copy may be furnished, with the consent of the student concerned, to requesting civilian institutions. Except for graduation, a copy of all other evaluations will be forwarded to HQDA, OTSG, ATTN: DASG-PSZ-MG.

6-26. Use of DA Form 67-9

Trainee evaluation summary reports are not to be substituted for the proper use of DA Forms 67-9 and 67-9-1 (Officer Evaluation Support Form) as outlined in AR 623-3, appendix H.

Section IV

Continuing Medical Education for Medical Corps Officers

6-27. Introduction

a. This section provides guidance for administering and operating a continuing medical education (CME) program for MC officers. It also describes standards and criteria needed to plan, develop, and conduct CME programs for physicians in Active Army/RC AMEDD facilities.

b. The MEDCOM is accredited by the Accreditation Council for Continuing Medical Education (ACCME) as a sponsor of CME activities. Therefore, all MEDCOM policies and procedures pertaining to CME are in full accordance with ACCME requirements and Federal regulations. As an accredited sponsor, the MEDCOM may award AMA Physician Recognition Award (PRA) Category I credit for activities that are planned and conducted in compliance with the ACCME standards. The MEDCOM mission statement for CME describes the types of activities, target audience, and subject matter that are appropriate for its sponsorship. Entities within the AMEDD that are planning CME activities that are felt to be consistent with the mission statement and who wish to offer CME credit for participation may choose to work with the MEDCOM for sponsorship. Those interested should refer to current policies to ensure compliance with all requirements. MEDCOM will not sponsor any activity that fails to comply with all requirements.

c. The CME is defined under existing policy issued by TSG in accordance with principles and direction of the ACCME. Any activity for which credit is requested must meet the definition of CME to award credit. No entity may indicate on any certificate or other document sponsorship by MEDCOM for CME credit unless approved by HQDA, OTSG, ATTN: DASG-PSZ-M.

d. The CME is a separate function from GME. Programs should be planned and produced that address the needs of physicians who are not in residency training.

e. Numerous options are available to MC officers for CME participation. These include hospital-based activities, courses provided by other Federal organizations, short courses, and civilian institutions. MC officers are expected to meet licensure standards as prescribed by the state licensing authority, their specialty-specific boards, and participate in CME as part of their professional duties. They must ensure participation is documented to meet applicable credentialing and licensure authorities requirements.

f. The MC officers apply for short course training as prescribed by MOI issued by HQDA, OTSG, ATTN: DASG-PSZ-MC. Table 3-1 outlines the funding sources for all AMEDD personnel to attend short courses. Officers must have at least 1 year of service remaining after completion of the desired training.

g. Army personnel must conduct all activities according to the standards of ethics and conduct established by the DOD 5500.7-R and the Army. The ACCME standards do not address all the requirements that Army personnel must meet when accepting support from non-Federal sources. However, Army regulations and standards of ethics and conduct must prevail whenever there is conflict between ACCME and Army standards, unless ACCME rules are stricter. Army personnel are strongly encouraged to consult with their servicing ethics counselor prior to accepting any support from a non-Federal entity or beginning travel where support from a non-Federal entity is anticipated.

(1) The Army has strict guidelines that govern the acceptance of support from non-Federal sources. A non-Federal entity is generally a self-sustaining, non-Federal person or organization, established, operated, and controlled by any individuals acting outside the scope of any official capacity as officers, employees, or agents of the Federal Government.

(2) Entities planning activities who wish to accept support from non-Federal sources must follow guidelines

prescribed by Army policy documents and complete all required actions to receive such support. Gifts must be processed in accordance with current regulatory and policy guidance.

6-28. Medical Corps responsibilities

a. Commanders, through their CME committees and with guidance from MEDCOM, will plan; manage; and evaluate local CME programs.

b. Physicians will maintain records of their participation in CME programs and submit copies of CME certificates to their respective credentials offices for inclusion in their records.

6-29. Criteria

a. The CME activities must be sponsored by an accredited organization and be designated as AMA PRA Category I education by that organization in order to award AMA PRA Category I credit to participants.

b. The AMA PRA Category I activities can take a variety of forms including lectures, seminars, use of self-study materials, self-assessment programs, and audio-visual or computer based materials as long as they are designated as Category I.

c. To qualify as an approved CME program for which AMA PRA Category I credit may be awarded by MEDCOM, each type of program as defined under CME must meet the ACCME and MEDCOM requirements.

d. The MEDCOM, as an accredited provider, does not designate activities for AMA PRA Category II credit. Physicians should claim credit for appropriate AMA PRA Category II activities through the AMA.

6-30. Policy and procedures

a. Program selection and approval is as follows:

(1) Authority to award AMA PRA credit resides with MEDCOM as the accredited sponsor. Commanders of the MEDCOM and its MSCs, through the CME committees in their organizations, will plan and implement jointly sponsored programs with MEDCOM within their facilities in accordance with the ACCME requirements. Institutional officials must complete required documentation for all CME conducted in Army MTFs. The local CME director may approve activities to be jointly sponsored with MEDCOM. The commander will ensure that a complete record is maintained for each activity awarding Category I credit according to paragraph 6-29, above, for 6 years.

(2) Course directors for AC/RC AMEDD CME activities attended by physicians from more than one facility must complete and submit a planning document as prescribed by applicable CME guidelines to the MEDCOM CME office for review and approval of the activity for AMA PRA Category I credit. The planning documents must be submitted 45 days prior to the activity start date. These must be reviewed and approved before the activity is conducted. Approval and sponsorship cannot be given retroactively. An after-action report must be submitted following the conclusion of each course.

b. Deputy commanders for clinical services or CME director will submit an annual summary report as prescribed by applicable CME guidelines of MEDCOM sponsored CME activities within their commands as of the end of each FY. Negative reports are required. The report will be submitted to HQDA, OTSG, ATTN: DASG-PSZ-MC. It must arrive no later than 45 days after the completion of each FY.

c. Commanders and CME planners must maintain signed letters of agreement for all commercial sponsorship. Further references on CME policy and guidelines are detailed on the MEDCOM CME Web site: <https://apps.meds.mil/cmeweb/secured>.

Section V

The Surgeon General's Physician Recognition Award

6-31. Introduction

This section establishes The Surgeon General's Physician Recognition Award (TSG-PRA) for outstanding contributions to military medicine; it also provides for administration of the awards. TSG-PRA is special in that the award requires command nominations.

6-32. Scope and applicability

a. The annual TSG-PRA award provides personal recognition by TSG to three physicians who have made significant contributions to military medicine. These awards are intended to increase physician motivation for exceptional job performance. They are separate and distinct from any other awards that may be given for exceptional duty performance.

b. This award program applies to all commands, agencies, installations, activities, and organizations that have AD Army physicians assigned on a full-time basis.

6-33. Eligibility for awards

With the exception of officers in the GME program, any AD Army physician in the grade of captain through lieutenant

colonel may be nominated for the TSG-PRA. An otherwise eligible officer currently in the Army GME program may be nominated for exceptional performance as a military physician before entering GME training. Having once received the award, an individual is ineligible for future nomination. A physician should have at least one year of AD Service remaining at the time of nomination. Exceptions will be made on an individual basis. Generally nominations will be for duty performance for the year immediately preceding nomination deadlines.

6-34. Number and timing of awards

Three awards will be given each year, one each for the grades of captain, major, and lieutenant colonel. Nominations must be received no later than 30 August. Recipients will be funded through HQDA, OTSG, ATTN: DASG-PSZ-MG to receive the award at the JSGMESB.

6-35. Responsibilities for The Surgeon General's Physician Recognition Award

a. TSG. TSG is the awarding authority and will exercise staff supervision over the award nomination and selection process.

b. Commanders at all levels and consultants to TSG. Commanders at all levels and consultants to TSG will—

(1) Identify potential recipients and submit nominations accordingly. Staff surgeons at all major and lower non-medical command headquarters will assist commanders in the nomination process. With concurrence of these commanders, nominations may be submitted by staff surgeons.

(2) Publicize the award and its recipient when announced. Within security and privacy act requirements, publicity will emphasize duty performance and contribution to military medicine for which the award was given.

c. Corps-specific branch proponent officer (CSBPO) for MC. The CSBPO will fund a CME training opportunity for each recipient based on availability of funds.

6-36. Nomination procedures

Commanders, staff surgeons, and consultants to TSG identified in paragraph 6-35*b*, above, will submit nominations for the TSG-PRA directly to Headquarters, MEDCOM, ATTN: MCHO-CL-C, 2050 Worth Road, Suite 10, Fort Sam Houston, TX 78234-6010. Nominations will be made by memorandum as defined by the MEDCOM. A current curriculum vitae (CV) and officer record brief (ORB) should be included with each nomination.

6-37. Selection procedures

Nominations for the TSG-PRA will be considered by a board appointed by the Chief, MC and coordinated by Headquarters, MEDCOM, MCHO-CL-C. The board will review nominations, make recommended selections, and forward recommended selections to TSG for approval.

6-38. Continuing medical education opportunity for award recipients

a. CME training. Award recipients for the TSG-PRA are authorized to take part in a CME training opportunity based on availability of funds. The training, if taken, must be taken during the same FY in which the award is received.

b. Funding and orders. The CSBPO will provide a fund citation for issuance of TDY travel orders at the local command level.

6-39. Command and installation awards

Commanders and staff surgeons shown in paragraph 6-35*b* are encouraged to establish a similar PRA at local levels. These awards should provide additional recognition for exceptional duty performance. Local command or installation recipients may also be nominated for the TSG-PRA. However, local awards should not be used as the only basis for TSG-PRA nominations.

Section VI

The Surgeon General's Award for Military Academic Excellence (The Lewis Aspey Mologne Award)

6-40. Introduction

This section establishes the TSG Award for Military Academic Excellence. It also provides for administration of the award.

6-41. Scope and applicability

a. The annual TSG Award for Military Academic Excellence provides personal recognition to a physician for outstanding leadership in military/academic medicine. This prestigious award is separate and distinct from any other award that may be given to a physician for exceptional duty performance.

b. This award applies to all commands, agencies, installations, activities, and organizations that have AD Army physicians assigned on a full-time basis.

6-42. Eligibility for award

Eligibility for the TSG Award for Military Academic Excellence is as follows:

- a.* Eligibility is limited to MC officers on AD in the grade of colonel. General officers are not eligible.
- b.* Individuals nominated should exhibit a balance between leadership in military medicine and teaching.
- c.* Nominees should have demonstrated academic excellence through—
 - (1) Service as residency training PDs.
 - (2) Participation in research as evidenced by scientific publications.
 - (3) Holding office in national or international professional societies.

6-43. Number and timing of awards

One award is presented annually. Nominations must be received no later than 15 July of each year. The recipient will be funded through HQDA, OTSG, ATTN: DASG-PSZ-MC to receive award at the annual JSGMESB.

6-44. Responsibilities for award

- a.* The Surgeon General is the awarding authority and will exercise staff supervision over the award nomination and selection process.
- b.* Commanders, at all levels, and consultant to TSG will—
 - (1) Identify potential recipients and submit nominations accordingly.
 - (2) Publicize the award and its recipient when announced. Within security and privacy act requirements, publicity will emphasize duty performance and contribution to military medicine for which the award was given.

6-45. Nomination procedures

Commanders and consultants to TSG identified in paragraph 6-44*b*, above, will submit nominations for the TSG Award for Military Academic Excellence directly to Headquarters, MEDCOM, ATTN: MCHO-CL-C, 2050 Worth Road, Suite 10, Fort Sam Houston, TX 78234-6010. Nominations will be made by memorandum using figure 6-1, below, as a guide. A current CV and ORB should be included with each nomination.

E X A M P L E

MEMORANDUM FOR Commander, U.S. Army Medical Command,
ATTN: MCHO-CL-C , 2050 Worth Road, Suite 10, Fort Sam Houston, TX 78234-6010

SUBJECT: Nomination for The Surgeon General's (indicate which award is being recommended)

1. Under the provisions of AR 351-3, the following individual is nominated for subject award:

- a. Grade, name, and SSN:
- b. Organization of assignment:
- c. Inclusive dates for which recommended: (generally the year immediately preceding nomination deadline)
- d. Grade and duty assignment during the recommended period:

2. The following summary of the individual's duty performance provides the basis for this nomination.

a. Provide specific and factual information, giving concrete examples of exactly what the person did. Describe how it was done, what benefits or results were realized, and state why such results merit recognition by The Surgeon General.

b. Keep the narrative unclassified and not more than two pages in length. It should be suitable for use as a press release if the nominee is selected for the award.

3. A curriculum vitae and officer record brief are attached.

4. This nomination is not in contravention of AR 600-8-1.

AUTHORITY LINE (if applicable)

SIGNATURE BLOCK

Figure 6–1. Format for a nomination for The Surgeon General award memorandum

6-46. Selection procedures

Nominations for the TSG Award for Military Academic Excellence will be considered by a board appointed by the Chief, MC and coordinated by Headquarters, MECOM, ATTN: MCHO-CL-C. The board will review nominations, make a recommended selection, and forward the recommended selection to TSG for approval.

6-47. Continuing medical education training available for the award recipient

a. Award recipient for the TSG Award for Military Academic Excellence is authorized to take one CME training opportunity based on availability of funds. The CME, if taken, must be taken during the same FY in which the award is received. Application and funding will be in accordance with current FY published policy and procedures and is subject to funding availability.

b. The CSBPO will provide a fund citation for issuance of TDY travel orders at the local command level.

Chapter 7

Medical Service Corps Policy and Programs

Section I

General

7-1. Introduction

a. This chapter provides MS officers with information relative to education and training opportunities available to them. The MS is a heterogeneous group of officers and WOs with numerous, diverse AOCs. Accordingly, the MS is involved in a widely diversified training program.

b. Material presented in this chapter is meant to summarize this variety and, in some cases, amplify policies provided in this and associated training directives. The MS education branch, AHRC, encourages direct telephonic or written inquiries concerning education and training of MS officers.

7-2. Policies

The following policies pertaining to education and training apply within the MS:

a. *Military professional training sequence.* The general sequence for military professional training is discussed below.

(1) *The AMEDD OBLC.* Generally, MS officers will attend the OBLC before their first AD assignment. On occasion, some officers will move to their first AD assignment and then attend AMEDD OBLC as a TDY and return.

(2) *The CCC.* MS officers in career status will normally attend the resident AMEDD CCC between their fourth to seventh year of AFCS. Selected officers may apply for and, if selected, attend the CLC3 at Fort Lee, VA, or the Aviation Officer Advanced Course (AOAC) at Fort Rucker, AL. Application for these courses is with the MS education branch, AHRC.

(3) *The MEL 4 equivalent.* Officers are automatically considered for attendance at the resident course when they have attained the grade of major or captain (P) between their tenth and fourteenth years of AFCS. Because of the limited number of seats available for resident attendance, MS officers are encouraged to enroll in the Web based distance learning. To be eligible for the nonresident course, officers must have completed the CCC; be selected or promoted to major; and have between 8 and 18 years of AFCS. Waivers for AFCS may be granted by the Commandant, MEL 4 Equivalent Course.

(4) *The SSC.* All eligible MS officers will be considered for SSC attendance. Eligibility consists of lieutenant colonel or colonel and AFCS between 16 to 25 years. Officers on the SSC (AWC) OML are encouraged to apply for the AWCDEP.

b. *Utilization tours for training.* A tour of duty using skills and knowledge developed by significant training experiences will normally occur immediately following the training. The major exception to this general policy is that utilization tours following the CCC are not required. Officers can request other long-term training immediately following the CCC.

c. *Methods of assessing needs.* All education and training opportunities within the MS are generated by need as assessed by the following methods:

(1) Long-course needs are determined through the validated requirements, procurement standards, and recognized requirements.

6-46. Selection procedures

Nominations for the TSG Award for Military Academic Excellence will be considered by a board appointed by the Chief, MC and coordinated by Headquarters, MECOM, ATTN: MCHO-CL-C. The board will review nominations, make a recommended selection, and forward the recommended selection to TSG for approval.

6-47. Continuing medical education training available for the award recipient

a. Award recipient for the TSG Award for Military Academic Excellence is authorized to take one CME training opportunity based on availability of funds. The CME, if taken, must be taken during the same FY in which the award is received. Application and funding will be in accordance with current FY published policy and procedures and is subject to funding availability.

b. The CSBPO will provide a fund citation for issuance of TDY travel orders at the local command level.

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b. Material presented in this chapter is meant to summarize this variety and, in some cases, amplify policies provided in this and associated training directives. The MS education branch, AHRC, encourages direct telephonic or written inquiries concerning education and training of MS officers.

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a. *Military professional training sequence.* The general sequence for military professional training is discussed below.

(1) *The AMEDD OBLC.* Generally, MS officers will attend the OBLC before their first AD assignment. On occasion, some officers will move to their first AD assignment and then attend AMEDD OBLC as a TDY and return.

(2) *The CCC.* MS officers in career status will normally attend the resident AMEDD CCC between their fourth to seventh year of AFCS. Selected officers may apply for and, if selected, attend the CLC3 at Fort Lee, VA, or the Aviation Officer Advanced Course (AOAC) at Fort Rucker, AL. Application for these courses is with the MS education branch, AHRC.

(3) *The MEL 4 equivalent.* Officers are automatically considered for attendance at the resident course when they have attained the grade of major or captain (P) between their tenth and fourteenth years of AFCS. Because of the limited number of seats available for resident attendance, MS officers are encouraged to enroll in the Web based distance learning. To be eligible for the nonresident course, officers must have completed the CCC; be selected or promoted to major; and have between 8 and 18 years of AFCS. Waivers for AFCS may be granted by the Commandant, MEL 4 Equivalent Course.

(4) *The SSC.* All eligible MS officers will be considered for SSC attendance. Eligibility consists of lieutenant colonel or colonel and AFCS between 16 to 25 years. Officers on the SSC (AWC) OML are encouraged to apply for the AWCDEP.

b. *Utilization tours for training.* A tour of duty using skills and knowledge developed by significant training experiences will normally occur immediately following the training. The major exception to this general policy is that utilization tours following the CCC are not required. Officers can request other long-term training immediately following the CCC.

c. *Methods of assessing needs.* All education and training opportunities within the MS are generated by need as assessed by the following methods:

(1) Long-course needs are determined through the validated requirements, procurement standards, and recognized requirements.

(2) Short-course needs are determined by a series of annual needs assessments using input from the field, MS specialty consultants, and the MS branch, AHRC.

d. Precedence of military programs. Military programs through which graduate degrees are awarded take precedence over all similar civilian programs because of the direct applicability of these programs to the AMEDD. Examples of these military programs are listed below.

- (1) Logistics Executive Development Course/Florida Institute of Technology (LEDC/FIT).
- (2) U.S. Army-Baylor University Graduate Program in Health Care Administration (HCA).
- (3) Biochemistry/Microbiology Doctoral Programs at USUHS.
- (4) Military Medical History Master's Program at USUHS.
- (5) Strategic Intelligence at the Defense Intelligence College.

e. Training selections. Long-term training selections are made through a formal board process convened by the Director, OPMD, AHRC, for degree programs and the chief, MC branch for non-degree programs. Attendance at short courses is approved within by the MS program manager, MS branch, AHRC. Funding is based on current published FY policy and procedures.

f. Constructive credit. MS officers can apply for constructive credit for military courses under AR 350-1, based on experience and other training. Approval of constructive credit is extremely limited because of opportunities available for MS officers to attend the resident CCC and enroll in the nonresident MEL 4 Equivalent Course. Constructive credit is awarded through a formal board process convened by the commander, AHRC.

Section II

Training Programs

7-3. Short-course education and training

a. A wide variety of training opportunities exists for MS officers in the following five categories:

(1) *Other Army.* These are courses conducted at various Army Service schools to include military training courses such as C4, airborne, air assault, planning, programming, budgeting, and execution (see DA Pam 351-4 for a complete listing).

(2) *Other Federal.* These are courses sponsored by the U.S. Air Force, the U.S. Navy, the Centers for Disease Control, and other Federal agencies. Examples include: Nuclear Hazards Training Course, Medical Effects of Nuclear Weapons, and Interagency Institute for Federal Health Care Executives (IIFHCE).

(3) *Civilian institution.* These include short courses offered by a variety of private organizations and institutions.

(4) *The AMEDDC&S functional courses.* These provide selected MS officers with specific learning experiences consistent with the MS officer's current or projected assignment (for example, patient administration, medical logistics management, health services human resources manager, and DOD pest management).

(5) *The PPSCP.* These courses are sponsored by the OTSG (annually or biennially) covering a wide variety of AMEDD specialty areas (for example, world wide patient administration symposium, Biennial Medical Entomology Course, Federal Services optometry, and Army medical evacuation). Individuals normally will be given priority if they have not attended a short course in the past year. Funding is based on current published FY policy and procedures.

b. Officers must have at least 1 year of service remaining after completion of the desired training.

c. With the exception of the CCC, officers are encouraged to meet training needs through correspondence courses. DA Pam 350-59 provides detailed information concerning availability of courses and application procedures.

d. Additional guidance is provided for the following training opportunities not addressed in paragraph 4-9:

(1) *Battalion/brigade Pre-Command Course (PCC).* MS officers selected (by the command designated position list board process) for lieutenant colonel and colonel-level command are required to attend the AMEDD PCC and the brigade/battalion PCC at Fort Leavenworth, KS. Other courses may be required depending on the command. Point of contact for further guidance is MS branch, AHRC.

(2) *IIFHCE.* A two-week course offered in the spring and early fall, the institute presents knowledge and provides a forum on pertinent health care issues within the Federal health care delivery systems. Selection for attendance at this course is made by the chief, MS branch, AHRC. Officers serving in, or on orders to, a MEDCEN or MEDDAC chief of staff or high-level staff position are considered.

7-4. Long-term health education and training

A wide variety of long-term training opportunities are available to every MS officer. Funding is based on current published FY policy and procedures. Specific dates for boards or selection panels and application deadlines are announced annually by DA message. Selections for these programs are made on a best-qualified basis. Long-course training includes the following:

a. Professional military education (for example, SSC, AWCCSC, CSC). Officers are not required to apply for this Category of training except for AWCCSC. Selection for resident attendance is made by formal selection board process.

Eligibility for all these programs is announced by DA message each year. MS officers are encouraged to discuss this significant category of training with their respective career manager.

b. Selection and training of MC aviators. Officers are selected for aviation training by a centralized board which is announced by message annually. Officers must meet the following criteria to be eligible for consideration:

- (1) Have less than 48 months AFCS at the start of flight training.
- (2) Be eligible for PCS.
- (3) Be less than 30 years of age at the start of flight training.
- (4) Meet the medical standards of AR 600–9.
- (5) Achieve a minimum score of 90 on the Flight Aptitude Skills Test.

c. The LTHET. Numerous opportunities exist for graduate-level training in those disciplines for which the MS has validated requirements. Specific disciplines and deadline dates with supplemental information are announced by an annual DA message released during the second quarter of the FY. Separate messages are released for degree and programs.

(1) *Application procedures.* Officers and WOs must apply in the timeframe noted in the annual messages. In addition to requirements of paragraph 4–4, the following procedures apply:

(a) Memoranda of recommendation will not be accepted. Officers may communicate with the president of the board by addressing a memorandum to: President, LTHET Selection Board, ATTN: AHRC–OPH–MS, 200 Stovall Street, Alexandria, VA 22332–4170. Supporting documents may be enclosed. Normally, the memorandum is used to communicate significant errors or omissions in an individual’s official military personnel file.

(b) Academic program descriptions must adequately describe the requested program and include precise registration and program beginning and ending dates. Federal facilities will determine program lengths and set beginning and ending dates, if known.

(c) The GMAT, GRE, or Miller Analogies scores are required with all degree program applications.

(d) Officers need not apply to schools before the selection board or panel convenes. Selections will be contingent on gaining admission to a college or university acceptable to DA. Officers may apply to universities if they desire, and may include letters of admission with their applications.

(e) Officers assigned to the AMEDDC&S student detachment will be rendered Academic Evaluation Reports under AR 623–1.

(2) *Eligibility.* In addition to eligibility criteria established in paragraph 4–3, officers—

(a) The MS officers who intend to apply for LTHET must be graduates of the C3 or CCC. Exceptions to the eligibility criteria are for clinical laboratory officers and blood bank fellows.

(b) Who are holding primary AOC 67J and applying for master’s-level training must have completed the initial six-year ADSO incurred as a result of flight training. If applying for doctorate-level training, officers must voluntarily withdraw from the flight program under AR 600–105. If selected for training, a statement to this effect must be included in the application.

(c) Must meet the minimum DA stabilization policy. This is 24-months time-on-station in CONUS or completion of an OCONUS tour under AR 614–30 unless a waiver is granted.

(3) *Selection of school.* Officers selected by the LTHET Selection Board must gain acceptance to a college or university that is regionally accredited by an appropriate agency and acceptable to DA. Also, consensus must be reached among the officer concerned; the appropriate specialty consultant; and the MS branch as to which institution will be attended.

d. Long-term training programs unique to the MS. The following are examples of long-term training programs unique to the MS. Not all programs are offered each year. Funding is based on current published FY policy and procedures. Announcement of programs is made in the training messages released in the 2d quarter of the FY.

(1) *Pharmacy.* A 1-year residency in pharmacy specialties is available to AD pharmacy officers and new officer accessions who qualify for a commission as a pharmacist. An AD officer will not be in competition with a new accession as the ceiling for residency positions has been increased to accommodate this recruiting tool. New accessions will not be offered residencies until after AD officers have been selected. AD officers should refer to the annual message on LTHET to determine eligibility criteria and specialty residencies offered.

(2) *Clinical Laboratory Officers Course (CLOC).* A 1-year course for officers with strong scientific undergraduate backgrounds that will qualify selected officers for classification and assignment as clinical laboratory officers. To apply, officers must meet—

(a) Academic requirements delineated by the CLOC director, Walter Reed Army Medical Center (WRAMC).

(b) DA Pam 351–4 requirements.

(3) *Blood Bank Fellowship Program.* An eighteen-month master’s program at WRAMC for qualified clinical laboratory officers that develops skills and knowledge necessary in operating the Army Blood Bank Program.

(4) *Three-year podiatric residency.* Graduates of civilian podiatry programs may apply for a 3-year podiatry residency offered by the Army immediately following graduation.

(5) *Social Work Advanced Program in Family Studies*. Social Work Advanced Program in Family Studies is a 2-year fellowship at WRAMC that specializes in care and treatment of the family unit.

(6) *Psychology*. Psychology Fellowship in Neuropsychology, Child/Pediatric Psychology, and Health Psychology.

(7) *Clinical Psychology Internship*. Information about this program is in DA Pam 611-21.

(8) *Optometry Residency*. A two year program that combines a residency in family practice optometry with an M.B.A. The business education provides a strong foundation in management, and the residency provides an opportunity to gain clinical experience and expertise in one or more areas of specialization within family practice optometry.

(9) *Procurement Officer's Internship*. A two-year program to provide the AMEDD with skilled personnel in career program 14 (contracting).

(10) *Comptroller Internship*. A fourteen month program of study that provides future resource managers with conceptual perspectives, practical and analytical tools and management skills.

(11) *Human Resources Internship*. A one-year program to provide a human resources professional with an orientation to corporate and strategic human resources management within the AMEDD.

e. Waivers of eligibility criteria. Officers may request waivers of eligibility criteria for various long-term programs. To request waivers, officers must demonstrate full justification of why the criteria do not apply in their situation. Requests will be submitted in memorandum format, along with their applications, to the chief, MS branch (AHRC-OPH-MS).

f. Warrant officer LTHET. The LTHET message will announce if program starts are available for WOs for bachelor degree completion or master's programs. WOs interested in LTHET should apply in accordance with the LTHET messages released in the second quarter of the FY.

g. U.S. Army Medical Materiel Agency (USAMMA) Medical Logistics Management Internship. Selection for this 6-month logistics course is made by a formal selection board. The board selects officers for the following July start and January start. Officers should apply for the course dates that they desire. Selected officers will be slated within the MS branch. Courses will be announced by annual DA message.

h. Procurement Officer Course Internship Program. Selection for this 2-year logistics training course is made by a formal selection board, with training starting on or about 1 July. Eligibility requirements and application procedures are as announced in an annual DA message.

7-5. New programs

A request to establish a new training program at an Army MTF must follow the procedures outlined in this regulation as well as local MTF coordination procedures.

Section III

Continuing Health Education Programs

7-6. Continuing health education details for the Medical Service Corps-general

This section provides guidance to help MS officers meet the requirements for the CHE program. It should also help them obtain and maintain professional credentials.

7-7. Professional organizations

a. List. The list below contains a compilation of professional organizations available to MS officers for professional enrichment and credentialing.

(1) *Administration*.

(a) American Academy of Medical Administrators.

(b) American College of Hospital Administrators.

(c) American Management Association.

(d) American Medical Records Association.

(e) American Public Health Association.

(f) Association of Clinic Managers.

(g) Healthcare Financial Management Association.

(h) American College of Health Care Executives.

(i) Society for Human Resource Management.

(j) Medical Group Management Association.

(2) *Audiology*.

(a) American Speech Language/Hearing Association.

(b) Council for Accreditation in Occupational Hearing Conservation.

(c) American Academy of Audiology.

(d) National Hearing Conservation Association.

(3) *Behavioral sciences*.

- (a) American Association of Marriage and Family Therapy.
- (b) American Association of Sex Educators, Counselors, and Therapists
- (c) American Hospital Association
- (d) American Psychological Association.
- (e) National Association of Social Workers.
- (f) Council on Social Work Education
- (4) *Biological sciences.*
 - (a) American Association for Clinical Chemistry.
 - (b) American Association for Immunology.
 - (c) American Association of Advanced Sciences.
 - (d) American Association of Blood Banks.
 - (e) American Chemical Society.
 - (f) American Physiological Society.
 - (g) American Society for Microbiology.
 - (h) American Society for Tropical Medicine and Hygiene.
 - (i) American Society of Clinical Pathologists.
 - (j) American Society of Parasitologists.
 - (k) American Society of Medical Technologists.
 - (l) Society of Forensic Toxicologists.
- (5) *Biomedical maintenance.*
 - (a) Certified Biomedical Equipment Technician.
 - (b) Certified Lab Equipment Specialist.
 - (c) Certified Radiology Equipment Specialist.
 - (d) Certified Clinical Engineer.
 - (e) Veterans Administration Certification.
- (6) *Computer sciences.*
 - (a) Association for Systems Management.
 - (b) Association of Computer Machinery.
 - (c) Data Processing Management Association.
 - (d) Operations Research Society of America.
- (7) *Entomology.* Entomological Society of America.
- (8) *Environmental/sanitary engineering.*
 - (a) American Academy of Environmental Engineers.
 - (b) American Academy of Industrial Hygiene.
 - (c) American Academy of Sanitarians, Incorporated.
 - (d) Board of Certified Safety Professionals.
 - (e) Conference of Federal Environmental Engineers.
 - (f) International Hazard Control Manager.
 - (g) National Environmental Health Association.
 - (h) Society of American Military Engineers.
 - (i) American Industrial Hygiene Association.
 - (j) American Conference of Governmental Industrial Hygienists.
- (9) *Health facilities design/management.* National Council of Architects Registration Board.
- (10) *Logistics.*
 - (a) Certified Professional in Health Information and Management Systems.
 - (b) Certified healthcare executive.
 - (c) Certified professional contracts manager.
 - (d) Certified Federal contract manager.
 - (e) National Society of Professional Engineers.
 - (f) Certified healthcare environmental services professional.
 - (g) Certified materials resource professional.
 - (h) Defense Acquisition Certification - Level III.
- (11) *Optometry.*
 - (a) American Optometric Association.
 - (b) American Academy of Optometry.
 - (c) Armed Forces Optometric Society.

- (12) *Pharmacy*.
 - (a) American Pharmaceutical Association.
 - (b) American Society of Hospital Pharmacists.
- (13) *Health physics*.
 - (a) American Board of Health Physics.
 - (b) American Board of Radiology.
 - (c) American Board of Medical Physics.
- (14) *Podiatry*. American Board of Podiatric Surgery.
- b. *MS officer responsibilities*. MS officers will—
 - (1) Communicate directly with professional accrediting organizations.
 - (2) Determine if specific training experiences, attended or scheduled, meet the requirements of the organization where credentialing is maintained.
 - (3) Maintain records of their attendance of CHE experiences.

Chapter 8

Army Nurse Corps Policy and Programs

Section I

General

8–1. Introduction

This chapter provides information concerning education and training opportunities available to AN officers. Professional military nursing includes the practice areas of clinical specialization, education, research, and nursing administration. AN officers have a responsibility to enhance their knowledge and skills as professional military officers and as professional nurses. The information presented in this chapter summarizes the variety of educational programs available and amplifies policies provided in this and associated training directives. AN branch, AHRC (AHRC–OPH–AN) and the nursing education branch (MCCS–HEN), Department of Health Education and Training, Academy of Health Sciences, encourages active participation by officers in planning this aspect of their careers.

8–2. Policies

- a. The general sequence of professional military education is as follows:
 - (1) *AMEDD OBLC*. All AN officers will attend the AMEDD OBLC before their first AD assignment. RC AN officers will attend OBLC (RC course) within 3 years of commissioning.
 - (2) *AMEDD CCC*. Due course AN officers will generally attend the resident CCC between their fourth and seventh year of AFCS. Officers who do not enter the ANC as second lieutenants may need to attend CCC earlier than the four year mark. These “non-Due Course” officers should contact their chief nurse and or AN branch manager to discuss an appropriate time line from attendance at CCC. Officers must hold the grade of captain or first lieutenant (P) to enroll in the non-resident Phase I AMEDD CCC. Phase I completion is necessary for enrollment in Phase II. RC AN officers are encouraged to attend non-resident CCC.
 - (3) *MEL 4 Equivalent Course*. Due course AN officers who have completed CCC, attained the grade of major or captain (P), and are serving between their tenth and fourteenth year of AFCS will be considered for resident attendance at the MEL 4 equivalent course. All eligible officers are encouraged to enroll in either the nonresident correspondence course or the USAR course. To be eligible for the nonresident course, officers must be CCC graduates and have less than 18 years of AFCS. However, non-due course officers may attend before their eighth year of AFCS. Waivers can be granted by the Commandant, MEL 4 Equivalent Course, to a minimum of 7 years and a maximum of 24 years. Officers who complete the nonresident course and desire not to be considered for the resident course must submit their request in writing to AHRC, ATTN: AHRC–OPH–AN before 1 May each year.
 - (4) *SSC*. All eligible AN officers will be considered for SSC attendance. Eligibility consists of grade of lieutenant colonel or colonel and AFCS between 15 to 22 years. Officers on the SSC (AWC) OML are encouraged to apply for the AWCDEP.
- b. Normally, a tour of duty using skills and knowledge developed by the training experience will occur immediately following military education. However, officers can seek other long-term training needs immediately following the AOAC.

8–3. Educational opportunities

- a. All education and training opportunities within the AN Corps are generated by need as assessed by the following methods:
 - (1) Long-course needs are determined through validated requirements.

Chapter 2

Overall Guidance for Army Medical Department Education and Training

Section I

General

2-1. Training in civilian (non-Federal) institutions

Training of AMEDD personnel in civilian (non-Federal) institutions is designed to augment educational experiences conducted in AMEDD military treatment facilities (MTFs) and other Federal training institutions and to meet established validated requirements, procurement standards, and/or a recognized requirement for which training is not readily available at a Federal facility. Applications for schooling will be approved contingent on requirements for training, individuals qualifications, and availability of funds.

2-2. Training in Federal facilities

Information pertaining to training of AMEDD personnel in Federal facilities is as follows:

- a.* Applications for schooling will be approved contingent on requirements for training, individual qualifications, and availability of funds.
- b.* Scope and prerequisites for training in U.S. Army facilities are in DA Pam 351-4. The scope and prerequisites for training in other Federal facilities are listed in training publications of the U.S. Public Health Service, the Office of Personnel Management (OPM), the Uniformed Services University of the Health Sciences (USUHS), the U.S. Navy, and the U.S. Air Force. When special application forms are specified for other than AMEDD courses, these forms should be completed and submitted according to paragraph 4-4.
- c.* Military commands are authorized to communicate directly with the sponsoring agency or course sponsor concerning detailed information about scope and content of a specific course.
- d.* Officers will apply for attendance to the AMEDD Captains Career Course (CCC). Selections for attendance at the Military Education Level (MEL) 4 Equivalent Course, and Senior Service College (SSC) are made at Department of the Army (DA) level after considering all eligible officers.

2-3. Quotas

- a.* Officer and EN quotas for AMEDD training in Army schools, other Federal agencies, and other institutions are obtained and monitored by Department of Health Education and Training (DHET), AMEDDC&S, based on availability of funds.
- b.* Non-funded quotas for attendance at AMEDD-sponsored Professional Postgraduate Short Course Program (PPSCP) courses by the U.S. Army Reserve (USAR), the Army National Guard (ARNG)/Army National Guard of the United States (ARNGUS) officers and EN personnel (active duty for training (ADT) only), and other non-Army attendees are distributed by DHET.

2-4. Army Weight Control Program

All Army personnel selected for training under this regulation must comply with AR 600-9 as appropriate. Assignment instructions will include a statement that the Soldier must comply with standards in AR 600-9.

2-5. Foreign national participation

The participation of foreign nationals in professional education and training programs of the AMEDD is governed by the Arms Export Control Act, as amended; The Foreign Assistance Act of 1961, as amended; and AR 12-15/NAVINST 4950.4/AFR 50-29. All requests for foreign national participation in professional educational and training programs are to be forwarded to Headquarters, Department of the Army, ATTN: DASG-HCZ-IP, 5109 Leesburg Pike, Falls Church, VA 22041-3258.

Section II

Active Duty Service Obligation

2-6. Introduction

- a.* Active duty Service obligations (ADSOs) are governed by DODI 6000.13. This regulation is not intended to supersede or DODI 6000.13. There are two basic purposes for ADSOs. ADSOs help the Army effectively manage its resources by maintaining an experienced, well-qualified officer Corps. ADSOs incurred because of promotion to certain grades, permanent change of station (PCS), or by acceptance of career status are designed to enhance stability in the officer force.
- b.* This section prescribes policies governing ADSOs incurred for participation in long-term health and health-related education and training programs. The following terms apply to policies described in this chapter.
 - (1) *AMEDD officers.* Those officers and WOs serving in the Army Nurse Corps (AN), Dental Corps (DC), Medical

Corps (MC), Army Medical Service Corps (MS), Specialist Corps (SP), Veterinary Corps (VC), and those members in Department of Defense (DOD) programs leading to or requiring commissioning in any of the above Corps.

(2) *First-term personnel*. Except as noted in DODI 6000.13, all health professions officers, from subsidized or non-subsidized procurement programs, who are either entering active duty (AD) for the first time or are entering AD after legally having served all prior military Service relationships. Members of the Selected Reserve (SELRES), the Individual Ready Reserve (IRR), the Stand-By Reserve, and the Retired Reserve who enter or reenter AD are excluded from the first-term personnel Category. Non-subsidized members include those who enter AD by direct appointment, reentry (recall), and deferred commissioning programs.

(3) *Graduate professional education (GPE)*. GPE includes internships, residencies, and fellowships in their respective professional fields for all AMEDD officers. ADSOs for GPE will be in accordance with DODI 6000.13.

(4) *Long-term health education and training (LTHET)*. Full-time, DOD-subsidized (military-sponsored) health or health-related education or training in a military or civilian facility of 26 weeks or more including education or training received in preparation for commissioning as a health professions officer (for example, medical school) and subsequent commissioning (for example, GPE).

2-7. Minimum terms of Service and active duty Service obligations for health professions officers

a. The minimum term of Service (MTS) for first-term personnel will be two years following internship for physicians and three years for other health professions officers. The minimum term is not additive to ADSOs incurred for education and training. Prior AD and internship or any other initial qualifying training program may not count toward fulfilling the MTS. ADSOs will be assigned in accordance with DODI 6000.13.

b. No portion of an ADSO may be satisfied as follows:

- (1) By prior military Service.
- (2) During any period of LTHET.
- (3) Concurrently with any other ADSO or with an obligation incurred for DOD-subsidized, pre-professional (undergraduate) education or training or prior long-term health or health-related education or training.
- (4) Except as otherwise provided below, ADSOs are governed by Federal statutes, DOD guidance, and terms established by the Secretary of the Army.

c. The ADSOs for GPE for physicians, dentists, and veterinarians (includes only residencies and fellowships) will be as prescribed by current DOD guidance and applicable contracts.

(1) The ADSOs for participation in medical internship programs and Advanced General Dentistry 1-Year Program (AGD-1) will be prescribed by current DOD guidance and applicable contracts.

(2) The ADSOs for participation in dental residencies and graduate training programs will be prescribed by current DOD guidance and applicable contracts and applicable contracts.

d. The ADSOs for all other LTHET programs will be as follows:

(1) Participants of partially-funded, long-term undergraduate (leading to a baccalaureate degree), or partially funded education and training in a civilian institution (participants receive only pay and allowances from the Army) will incur an ADSO as prescribed by current DOD guidance. Participation for periods in excess of two years will result in an ADSO as prescribed by current DOD guidance.

(2) Participants of fully-funded, long-term undergraduate (leading to a baccalaureate degree), or fully-funded education or training in a military or civilian institution (participants receive pay and allowances plus tuition and other authorized reimbursable expenses from the Army), will incur an ADSO as prescribed by current DOD guidance.

(3) Participants of long-term graduate (leading to a master's or doctoral degree) education and training in a military or civilian institution will incur an ADSO as prescribed by current DOD guidance.

(4) For exceptional ADSOs, the ADSO for the Physician Assistant Training Program is 4 years or based on current Army Medical Specialist Corps policy. The ADSO for the 1-year pharmacy residency program is 3 years or as prescribed by current DOD guidance.

(5) The ADSO for U.S. Army-Baylor University Graduate Program in Health Care Administration is as prescribed by current DOD guidance. Payback of the ADSO begins after completion of the didactic phase of the training.

(6) The ADSOs for training with industry (TWI) are equal to 2 years or 3 times the length of schooling, computed in days, whichever is greater.

(7) The ADSOs for military internships are equal to three times the length of schooling, computed in days, whichever is greater.

e. Reimbursement is done as follows:

(1) Officers must reimburse the Government for costs of advanced education for participation in the fully-funded LTHET program (including LTHET fully-funded residencies and fellowships) if they voluntarily leave the program (including separation as a conscientious objector) or because of misconduct or other reasons, fail to complete the ADSO set forth in this regulation and in their training agreement. The term "fail to complete" means completing a portion or none of the required period of Service on AD. Costs of advanced education include tuition, books, supplies,

and other education costs incurred by the Government. They do not include pay, allowances, or travel expenses unless otherwise specified in this regulation, DODI 6000.13, or law. Interest on reimbursement of advanced education costs may further be assessed under other existing law or in accordance with DOD guidance. The reimbursement amount will be determined under the formula in figure 2–1, below.

$$\frac{\text{Cost of advanced education} \times \text{Unserved portion of ADSO}}{\text{Total fully-funded Long Term Civilian Training program ADSO}}$$

Figure 2–1. Reimbursement formula for failure to complete active duty Service obligation

(2) Participants in the Armed Forces Health Professions Scholarship Program (AFHPSP) and/or Financial Assistance Program (FAP) must reimburse the Government as prescribed by law, current DOD guidance, and the service agreement (SA) if they fail to complete the ADSO incurred for participation in the programs, as determined by the SA.

2–8. Active duty Service obligations for health care incentive programs

a. Armed Forces AFHPSP/FAP. Each participant will incur an ADSO or alternative obligation as prescribed by law, current DOD guidance, and the SA, as determined by the SA.

b. USUHS. Physician graduates of the USUHS School of Medicine will incur an ADSO of seven years, except as noted below.

(1) Graduates who spend less than 4 school years at USUHS will incur an ADSO of 21 months for each year or portion thereof, but in no case will the minimum ADSO be less than 27 months.

(2) Graduates who repeat a year or portion of a year for academic or other reasons and are delayed in graduation will incur an additional ADSO of 1/2 year for each additional 1/2 year or portion thereof for such repeated work.

(3) A participant who is dropped prior to program completion will incur an ADSO equal to the period of participation or one (1) year, whichever is greater.

(4) An alternative obligation may be imposed for participants who fail to complete the ADSO.

2–9. Modifying active duty Service obligations

a. Most ADSOs are established by law, DOD policy, and terms established by the Secretary of the Army (and typically promulgated in contract). Additionally, ADSOs are typically based on the terms of a program and are not tailored to fit an individual. Given these factors, requests to change the non-statutory ADSO for a certain program should follow the guidance below.

b. Requests to modify the ADSO of a specific program, except AFHPSP/FAP/GME/USHUS, may be made in memorandum form with necessary supporting documentation. All requests must be forwarded through command channels to the appropriate consultant and AMEDD Corps chief. AMEDD education program managers will consolidate requests for modified ADSOs at Academy of Health Sciences, Department of Health Education and Training (DHET), 1750 Greeley Road, Suite 201, ATTN: MCCS–HE, Fort Sam Houston, TX 78234–5075, for staffing across Corps and AMEDD Personnel Proponent Division (APPD) and then forward the request to the Office of The Surgeon General (OTSG) for final approval.

Chapter 3

Professional Training of Army Medical Personnel

Section I

General

3-1. Scope

a. This section prescribes the responsibilities, policies, procedures, and prerequisites governing the professional development and qualification of AMEDD personnel through the following:

- (1) Programs of formal education and training at Army medical treatment facilities.
- (2) Non-AMEDD Army schools.
- (3) Federal facilities.
- (4) Civilian educational institutions, industries, or organizations.
- (5) Continuing health education programs designed to maintain and enhance professional competencies through continued learning and professional specialty recognition programs.

b. This education and training is authorized by Title 10 United States Code, Section 4301 (10 USC 4301).

3-2. Corps-specific education and training policies

Corps-specific education and training policies are listed in the following chapters:

- a.* For Dental Corps (DC), see chapter 5.
- b.* For Medical Corps (MC), see chapter 6.
- c.* For Medical Service Corps (MS), see chapter 7.
- d.* For Army Nurse Corps (AN), see chapter 8.
- e.* For Army Medical Specialist Corps (SP), see chapter 9.
- f.* For Veterinary Corps (VC) see chapter 10.
- g.* For Enlisted Corps (EN), see chapter 11.
- h.* For Chaplain Corps (CH), see chapter 12.

3-3. Funding and orders

a. Funding for necessary tuition for fully-funded LTHET will be provided by Academy of Health Sciences, DHET, ATTN: MCCS-HEC, 1750 Greeley Road, Suite 201, Fort Sam Houston, TX 78234-5075. Health Services Division (for officer personnel) and Health Services Branch (for EN personnel), U.S. Army Human Resources Command (AHRC) will issue assignment instructions assigning officer and EN personnel to and from student status.

b. Funding for selected short course education and training attendees will be provided by Academy of Health Sciences, DHET, 1750 Greeley Road, Suite 201, ATTN: MCCS-HEC, Fort Sam Houston, TX 78234-5075. Temporary duty (TDY) orders will be prepared by the unit to which the attendee is assigned.

c. Funding for educational expenses is the responsibility of the unit to which the AD Soldier is assigned.

d. Headquarters, Department of the Army (HQDA) ATTN: DASG-PSZ-M, 5109 Leesburg Pike, Falls Church, VA 22041, is the approval authority for application of MC officers to attend selected short course activities. The Joint Service Graduate Medical Education Selection Board (JSGMESB) serves as the selection board for all MC LTHET activities.

Section II

Reimbursement of Training Expenses

3-4. Introduction

Active duty AMEDD personnel attending training under this regulation may be authorized payment for costs of specified educational expenses incurred as described in this section. Personnel enrolled in fully-funded, degree producing academic programs are eligible for payments of specific educational expenses. Categories of personnel who are not eligible for payments of educational expenses are those in—

- a.* Short-course training.
- b.* Partially-funded training programs in civilian institutions.
- c.* Non-degree producing training programs in civilian or Federal facilities.

3-5. Amounts authorized and payment procedures

a. Students enrolled in fully-funded, degree producing programs in civilian institutions will be authorized a single payment per academic year (AY) to defray cost of books and expendable supplies. Reimbursement is also provided for preparation of a master's degree thesis or a doctoral dissertation. The amounts authorized for reimbursements will be according to published fiscal year (FY) policy and procedures.

b. An AY is twelve months (or any portion thereof) and begins on the course start date. The annual book reimbursement stipend is payable once the Central Training Program Branch (CTP) of the AMEDDC&S has received the required documentation as described in Chapter 7 of the Handbook for Students found on the student detachment Web site. Chapter 7 of the Handbook for Students also describes which expenses are reimbursable and which ones are non-reimbursable. Procedures for reimbursement for a thesis or dissertation can also be found in chapter 7. Payments will not be paid for students who have been granted a LTHET extension.

c. Expenses for students enrolled in the U.S. Army Graduate Program in Anesthesia Nursing (6F-66F), U.S. Army-Baylor University Graduate Program in Physical Therapy (6H-65B), and U.S. Army-Baylor University Graduate Program in Health Care Administration (6H-70A) are paid by the AMEDD Center and School.

3-6. Funding authorities and procedures for continuing health education

a. Each person in the AMEDD requiring CHE according to the goals stated in each of the AMEDD Corps specific chapters, as listed in paragraph 3-2, is authorized to attend one funded CHE training experience each FY, subject to availability of funds. Courses conducted by the AMEDD for the primary purpose of CHE, and not included as DA mission essential or DA directed, will be counted against a person's limit of one funded CHE course each year. (DHET identifies these as health professional education courses in an annual message, "Professional Postgraduate Short Course Program (PPSCP).") For education not sponsored and identified by the AMEDD, the funding authority (see table 3-1, below) will determine if the experience is CHE as defined in the glossary. When CHE funding is not available, commanders may authorize permissive TDY under AR 600-8-10 at no expense to the Government.

Table 3-1
Continuing health education funding authorities for active U.S. Army Medical Department personnel

Type of CHE experience	AMEDD or other Federal course or conference ¹	Other Army course or conference	Private organization course or conference
Personnel assigned to	is funded by	is funded by	is funded by
1.MEDCOM units:			
a. Interns, residents and fellows in GME and GDE programs at Army facilities	HQ, MEDCOM, further delegated to MEDDAC/DENTAC/MEDCEN ²	DHET ³	HQ, MEDCOM, further delegated to MEDDAC/DENTAC/MEDCEN ²
b. Personnel in long-term civilian training and interns, residents, and fellows in GME or GDE programs at civilian facilities	DHET ³	DHET ³	DHET ^{3,4}
c.All other AMEDD personnel	DHET ^{3,4}	DHET ^{3,6}	HQ, MEDCOM, further delegated to MEDDAC/DENTAC/MEDCEN and other subordinate elements ⁷
2.Non-MEDCOM controlled units (for example, DOD, DA, FORSCOM, TRADOC)	DHET ^{3,4}	DHET ³	Parent Unit/DHET ⁵

Notes:

¹ The AMEDD and other Federal courses or conferences include AMEDD and tri-service short courses under the PPSCP. Also included are courses or conferences sponsored by other Federal agencies (for example, Armed Forces Institute of Pathology (AFIP)).

² The DHET may fund a resident or fellow who is a guest speaker or presenting a paper at an AMEDD or tri-service course conducted under the PPSCP.

³ Qualified AD personnel requesting DHET funding for CHE must submit a commander approved DA Form 3838 (Application for Short Course Training) to the appropriate program manager at DHET, 1750 Greeley Road, Suite 201, Building 4011, Fort Sam Houston, Texas 78234-5075. DA Form 3838 must arrive at least 60 days before the requested course or conference starting date.

⁴ Units may fund the attendance of assigned AMEDD personnel at AMEDD and other Federal courses or conferences when central funding from DHET is unavailable. Prior approval from the hosting facility and project officer is required.

⁵ Parent unit is the primary source of funding; central funding from DHET is subject to availability and other program priorities.

⁶ Within theater courses are funded by ERM/ERDC/18th MEDCOM.

⁷ Elements of OTSG and field operating agencies (FOAs) responsible for their own assigned personnel.

⁸ All funding is subject to availability.

b. Personnel must ensure competency in their professional practice. Lack of available Army funding for CHE does not relieve personnel from the responsibility for meeting these requirements.

c. A copy of certificates of training or other proper documents of professional continuing education (CE) will be maintained at the local level as outlined in the specific Corps chapters (see chaps 5 through 12.)

d. The AMEDD personnel attending civilian CHE in a TDY status will—

(1) Wear their military uniform during the conference or meeting.

(2) Visit the AMEDD procurement counselor exhibit areas, when appropriate, during the conference or meeting and provide any technical assistance that may be required.

e. The CHE applications for Active Army AMEDD personnel will be submitted on DA Form 3838 (Application for Short Course Training) through local command channels to the proper funding authority as shown in table 3–1, above, and also detailed below. Applications should arrive at the funding authority location no later than 60 days prior to the course or conference starting date.

(1) The Commander, MEDCOM, is the funding authority for attendance of AMEDD personnel assigned to Headquarters, MEDCOM, and its subordinate units at CHE programs conducted by—

(a) The AMEDD and other Federal activities for all interns, residents, and fellows participating in GME or graduate dental education (GDE) programs at Army facilities.

(b) Private organizations.

(c) The AMEDD facilities under the PPSCP when central funding is unavailable under paragraph 3–6e(3)(e), below, and for all courses sponsored locally or conferences conducted throughout the AMEDD.

(2) The DHET is the funding authority for attendance of AMEDD personnel for CHE programs conducted by—

(a) Private organizations for personnel assigned to commands or activities other than MEDCOM when parent organization funding is unavailable.

(b) The AMEDD facilities under the PPSCP except that interns, residents, and fellows participating in GME or GDE programs at Army facilities are funded by their parent organization unless they have been invited to make presentations at the courses.

(c) Other Federal activities except interns, residents, and fellows participating in GME or GDE at Army facilities are funded by their parent organizations, with the exception of Army pathology residents who are authorized attendance at the annual AFIP problems in anatomic pathology short course.

(d) The AMEDD, Federal, other Army, and private organizations for all AMEDD personnel in LTHET, and all residents and fellows participating in GME or GDE under Army sponsorship at civilian facilities.

(e) Other Army organizations for all AMEDD personnel regardless of parent organization.

(3) The USAR and ARNGUS funding authorities for their respective personnel.

(a) The ARNGUS AMEDD personnel will be funded by the National Guard Bureau (NGB). Funding depends on the availability of these Federal funds at state level. Applications for ARNGUS personnel for attendance at CHE courses will be submitted on DA Form 1058–R (Application for Active Duty for Training, Active Duty for Special Work, Temporary Tour of Active Duty, and Annual Training for Soldiers of The Army National Guard and U.S. Army Reserve) to the Army National Guard of the United States Readiness Center, ATTN: NGB-ART, 111 South Mason Drive, Arlington, VA 22204-1382. Applications should arrive not later than 60 days prior to the course or conference starting date.

(b) The USAR AMEDD personnel not on AD will be funded by USAR funds. The USAR program provides several modes for USAR personnel to attend an annual CHE experience.

(c) Each individual in the USAR AMEDD requiring CHE is encouraged to attend one funded, accredited CHE experience each FY subject to funding availability.

(d) Local programs must be used to satisfy most CHE requirements. Unit commanders may authorize attendance at CHE under AR 140–1 in a regular scheduled training status in lieu of AT funded by the unit, a USAR command, or the continental United States. Army (CONUSA).

(e) Centrally sponsored opportunities are announced annually depending on availability of funds. These programs are available to IRR, Individual Mobilization Augmentee (IMA), and Troop Program Unit (TPU) members. Selection of individuals will be made by AHRC, St. Louis. Applications will be submitted on DA Form 1058–R through command channels to Commander, AHRC, St. Louis, ATTN: AHRC–HS–CHE, 1 Reserve Way, St. Louis, MO 63132–5200. Applications should arrive not later than 45 days prior to the course or conference starting date. A copy of the program of study or other appropriate documentation of CHE approval must accompany all requests for ADT. Individuals must meet the standards in AR 135–200, chapter 7, to qualify for ADT.

designed to maximize the mobilization readiness and operational effectiveness of medical units and members. The objective of WARAMS is to fully integrate RC and Active Army medical units so that Soldiers who may work together in wartime and train together in peacetime. WARAMS promotes effective identification, organization, training, and operations of the total force medical assets (WARTRACE).

(4) *Medical readiness exercises (MEDREX)*. MEDREX are designed to allow RC medical units to participate fully with the Active Army in command post exercises and field training exercises. MEDREX attempts to increase operational readiness capabilities to meet wartime medical support requirements. For maximum effectiveness, exercises are conducted at actual wartime employment locations in the United States and in potential overseas theaters of operations. WARAMS and MEDREX provide a collective basis to achieve the highest level of medical readiness (for example, Ulchi Focus Lens, Reception Staging Onward Movement and Integration (RSO&I), Pacific Warrior, Cobra Gold, Golden Medic).

(5) *Programs for nurses and EN health care personnel*. Programs for nurses and other critically short health care specialists will accomplish objectives similar to those of physician reservists in medical universities and schools (PRIMUS). Military pay and retirement points will be credited while performing IDT or ADT at, or with, universities or schools and their branches or other designated locations for the following:

- (a) Completion of a master's degree.
- (b) Completion of a Bachelor of Science in Nursing.
- (c) Completion of an Associate Degree in Nursing.
- (d) Completion of courses that have a direct relation to mobilization and readiness.
- (e) Certification courses (for example, cardiopulmonary resuscitation, advanced cardiac life support, advanced trauma life support (ATLS), and so on).
- (f) Certification/licensure examinations.

13-5. Mandatory training activities

Unit commanders will prescribe that AMEDD personnel attend mandatory drills with their unit unless excused or exempt. This is to promote unit cohesion and to ensure participation in minimum mandatory training activities required of every Soldier in the unit. This policy should not be interpreted as requiring attendance at every, or even the majority, of drills. The intent is to assist in balancing the needs of the unit with the training requirements of the individual and the special situation involving the AMEDD Soldier. Each ARNGUS or USAR unit commander has full authority to grant all types of training flexibility afforded by the AMPC except for crossing geographical boundaries. Commanders are encouraged to exercise this authority whenever possible to promote unit cohesion and unit membership.

13-6. Training reports

a. Attendance at unit training will be recorded per AR 37-104-10. DA Form 1379 (U.S. Army Reserve Components Unit Record of Reserve Training) will be completed as required in AR 140-185.

b. The AMEDD personnel performing duty away from the unit or at a time different from the RSUTA will use sign-in rosters verified by the person in charge, if applicable. DA Form 1380 will be used as required in AR 140-1 and AR 140-185.

(1) The form must bear the signature of the officer or person in charge who supervised or had direct knowledge of the training (DA Form 1380, blocks 11 and 12).

(2) If the AMEDD Soldier is a civilian employee of the facility, the DA Form 1380 must be annotated to state that the duties performed were above and beyond any regularly scheduled duties and were performed in an appropriate uniform.

(3) If a military person cannot be named at a CHE meeting, a Soldier may state their attendance on the DA Form 1380. Officers who attend those meetings listed by TSG will add the following statement: "I have attended two session, each lasting four hours, at the time(s) and date(s) indicated within an approved meeting, seminar, convention, symposium, conference, or training session approved by The Surgeon General and hereby certify my justification for military pay and/or the award of retirement point credit under provisions of AR 140-1, AR 140-185, and NGR 680-2."

Chapter 14

Professional Boards and Certification of United States Army Medical Department Personnel

Section I

United States Army Medical Department Officers and Warrant Officers

14-1. General

Examinations and boards are required for specialty recognition of certain officers and WOs. This section prescribes payment (from appropriated funds) of fees and travel expenses for these examinations and boards. Payments will be

made for recognition by boards and comparable professional organizations. This section prescribes TDY for officers and WOs undergoing examinations for recognition. Funding will be in accordance with published FY policy and procedures.

14-2. Eligibility

An officer or WO must be eligible to be paid for expenses. Expenses (including TDY) must relate to examinations or boards. To be eligible, the officers or WOs must meet the requirements in paragraphs 14-2*a* and 14-2*b*, below, and must be on AD (other than AT or ADT). In cases when the requirements of 14-2*a*, below, are met, but 14-2*b* are not, commanders may authorize permissive TDY for persons to take examinations at no expense to the Government. The officer or WO must—

a. Arrange for examinations and boards for recognition with the proper specialty bodies. In some cases, a specialty body will not accept a candidate for an examination or board before receipt of an application fee. In such cases, a statement should be obtained from the specialty body that the candidate will be considered for acceptance upon receipt of such fee. To prevent denial of reimbursement, applicants are cautioned not to remit application fees before receipt of authorization (see para 14-6).

b. Have at least one-year AD remaining after the date of the specialty examination or board. If stationed overseas, enough service must also be available to permit completing the specified tour for the area of assignment.

14-3. Authorized payments

Payments are subject to paragraphs 14-2, above, and 14-5. They are also subject to the availability of local TDY funds. The local commander determines if funds are available. AMEDD officers and WOs are authorized payment for fees, necessary travel costs, and legitimate and documented costs associated with preparation of records for a board examination. Fees and costs must relate to examinations and boards for specialty recognition by recognized boards and comparable professional organizations as directed by DA. An examining board may require the presence of a patient. Thus, an assistant may be needed to deliver treatment effectively. If so, both a patient and an assistant for the examinees are authorized TDY travel and per diem (if determined eligible by the local commander). If a candidate fails to achieve recognition on the first attempt, permissive TDY (AR 600-8-10) may be authorized for later attempts. Funded TDY will not be authorized for second attempts. Fees authorized for payment under this regulation do not include those fees or dues for memberships of persons in societies or associations. Such membership fees or dues are not payable from appropriated funds. Funding will be in accordance with published FY policy and procedures.

14-4. Officers and warrant officers stationed overseas

a. Part I (written) of many authorized examinations is given in various overseas areas. DOD has named one of the military departments in each major overseas area to assist the specialty boards in giving part I of their examinations to officers and WOs stationed in that area. The areas and departments are listed in table 14-1, below.

Table 14-1
Overseas part I (written) examination authorities

Area	Department
Pacific	Army
Europe	Army
Mediterranean, North Africa, and Middle East	Navy
Alaska	Air Force

b. If part I of the examination is given in the officer's or WO's overseas area, the member will not be authorized to return to CONUS to take this part of the examination. This is true even though the member may otherwise be eligible for TDY to take specialty board examinations.

c. Officers or WOs serving in overseas areas where part I of the proper examination is not given may be placed on TDY to the places of examinations within the United States if the provisions of paragraph 14-2 are met.

d. It may be more economical for officers or WOs to take part I of the examination in an area other than the one where they are stationed. If so, the AMEDD AC or the command surgeon of the area will arrange with the responsible agency of the other area for them to take this part of the examination.

e. Part II examinations are generally oral or performance examinations. Part II examinations and examinations of boards having single or combined examinations are normally not given overseas. Officers and WOs may be placed on TDY to the place in the United States where such examinations are given if the provisions of paragraph 14-2 are met.

14-5. Authorization and reimbursement for personal expenditures

a. Prior authorization is required in all instances in which reimbursement for personal expenditures will be claimed under this chapter. Funding will be in accordance with published FY policy and procedures. Exceptions are in paragraphs 14-5*c* and 14-5*d*, below. The officer or WO will submit an application through command channels on a memorandum upon receipt of either of the following:

- (1) Evidence of acceptance for an authorized examination or board for recognition.
- (2) A statement from the specialty body showing that the officer or WO will be considered for acceptance upon receipt of the application fee.

b. The first commander processing the memorandum who is authorized to issue TDY orders will issue the orders according to AR 600-8-105. Funds for reimbursement of personnel taking examinations or boards in a TDY-en-route-to-PCS status will be provided by the losing organization except as described in paragraphs 14-5*c* and 14-5*d*, below. Operational funds available for the activity to which the officer or WO is assigned will be used for reimbursement of expenses relating to examinations or boards for recognition. Except for MC and MS, AMEDDC&S officers and WOs assigned to non-AMEDD controlled units or assigned to the Student Detachment will submit applications to Academy of Health Sciences, DHET, 1750 Greeley Road, Suite 201, ATTN: MCCS-HE, Fort Sam Houston, TX 78234-5075. MC officers should submit their applications to HQDA, OTSG, ATTN: DASG-PSZ-MC, 5109 Leesburg Pike, Falls Church, VA 22041-3258. MS officers should submit applications to Commander, U.S. AHRC, Health Services Division, ATTN: AHRC-OPH-MS, 200 Stovall Street, Alexandria, VA 22332-0417. Upon review and approval, a fund cite will be issued subject to the availability of funds. Orders will state that reimbursement is authorized according to this regulation upon submission of either of the following forms:

- (1) DD Form 1351-2 (Travel Voucher or Sub-voucher) (see para 14-6*a*).
 - (2) SF 1034 and SF 1034A (Public Voucher for Purchases and Services Other than Personal) (see para 14-6*b*).
- c.* Otherwise qualified officers or WOs who fail to obtain authorization before expending personal funds relating to examination or boards for recognition may be reimbursed. If so, the appropriate commander may authorize reimbursement of such expenses upon presentation of reasonable justification.
- d.* Otherwise qualified officers or WOs who fail to obtain written authorization before spending personal funds for travel relating to examination or boards for recognition may be reimbursed for that travel. Reimbursement of such expenses will be made if later confirmation is obtained in accordance with Joint Federal Travel Regulations (JFTR), Volume I.

14-6. Payment of fees

Officers and WOs will pay the application and examination or board fees for recognition directly to the examining bodies from personal funds. They will obtain a receipt to support their claim for reimbursement after the date of examination or board according to paragraphs 14-6*a* or 14-6*b*, below. Instead of the original receipt, the endorsed canceled personal check, or copy, may be submitted to support the claim.

a. When travel is involved, prepare a DD Form 1351-2 to claim reimbursement or travel costs incurred or fees paid. Include with DD Form 1351-2—

- (1) The original receipt or the endorsed canceled personal check, or copy, for the fee paid by the officer or WO.
- (2) Copies of the orders prescribed in paragraph 14-5*b*.

b. When travel is not involved, submit claims for reimbursement for fees on SF 1034 and SF 1034A. Include with the SF 1034 and SF 1034A—

- (1) The original receipt or the endorsed canceled personal check, or copy, for the fees paid.
- (2) A copy of written authorization (see para 14-5), or explanation of failure to obtain authorization (see para 14-5*c*).

Section II

United States Army Medical Department Enlisted Personnel

14-7. General

This section provides for payment from public funds of fees and other expenses relating to examinations or boards for allied health professional recognition of AMEDD EN personnel. Funding will be in accordance with published FY policy and procedures. Recognition will be by recognized boards and comparable professional organizations. TDY is authorized for AMEDD EN persons to undergo examinations relating to examinations or boards for such recognition. However, commanders will attempt to have the examiner come to the installation to administer the examination to large groups. When this is done, the examiner's fees and travel costs are paid from funds available for the operation of the facility where the examinations are given. Cite this regulation as authority.

14-8. Eligibility

To be eligible for reimbursement of expenses under this chapter, EN personnel must be on AD (other than AT or ADT). Funding will be in accordance with published FY policy and procedures. They must be performing duties of

their specialty. They must meet the requirements indicated in paragraphs 14–8*a* and 14–8*b*, below. When paragraph 14–8*b*, below, is not met, commanders may authorize permissive TDY for persons to take examinations at no expense to the Government. When paragraphs 14–8*a* and 14–8*b*, below, are met and members are stationed overseas, commanders may authorize TDY to CONUS only if they are unable to take the examination in the overseas area of assignment. EN personnel must—

- a.* Arrange for acceptance for examination or board for allied health professional recognition by specialty bodies.
- b.* Have at least one year AD remaining after the date of the examination.

14–9. Authorized payments

Payments for fees and necessary travel costs are subject to paragraphs 14–8, above, and 14–10, below, and the availability of local TDY funds. AMEDD EN personnel are authorized payment for fees and travel costs relating to examinations and boards for allied health professional recognition by recognized boards and comparable professional organizations as directed by OTSG. MSC commanders at the O–6 level may approve a certification testing when the certification is from a nationally certified board and the skills acquired through the certification process enhance the Soldier's ability to perform his or her duties. If a candidate fails to achieve recognition on the first attempt, permissive TDY may be authorized for later attempts. Funded TDY will not be authorized for second attempts, with the exception of the 91W/M6 licensed practical nurse licensure examination, which may be funded for second attempts. Fees authorized for payment under this regulation do not include those fees and dues for memberships of persons in societies and associations. Such membership fees and dues are not payable from appropriated funds.

14–10. Authorization and reimbursement for personal expenditure

a. Prior authorization of the commander described in paragraph 14–10*b*, below, is required when reimbursement for personal expenditures will be claimed under this chapter. EN personnel will submit applications through command channels on a memorandum when they receive either of the following:

- (1) Evidence of acceptance for an authorized examination or board for recognition.
- (2) A statement from the specialty body showing that they will be considered for acceptance upon receipt of the application fee.

b. Orders will be issued according to AR 600–8–105. The first commander processing the memorandum who is authorized to issue TDY orders will issue the orders. Operational funds available for the activity to which EN persons are assigned will be used for reimbursement of these expenses. Funds for reimbursement of personnel taking examinations or boards in a TDY-en-route-to-PCS status will be provided by the losing organization. Also, orders will state that reimbursement of expenses relating to examinations or boards is authorized according to this regulation. Reimbursement will be made upon submission of DD Form 1351–2 or SF 1034 and SF 1034A (see para 14–11*a* or para 14–11*b*, below).

14–11. Payment of fees

Enlisted personnel will pay the application and examination or board fees for allied health professional recognition directly to the examining boards from personal funds. They will obtain receipts to support their claims for reimbursement after the examination or board according to paragraph 14–11*a* or 14–11*b*, below. Instead of the original receipt, the endorsed canceled personal check, or copy, may be submitted to support the claim.

a. When travel is involved, indicate so on DD Form 1351–2 to include the travel costs incurred for the examination or board. Support DD Form 1351–2 with—

- (1) The original receipt or the endorsed canceled personal check, or copy, for the fee paid by the EN person.
- (2) Copies of the orders prescribed in paragraph 14–10*b*, above.

b. When travel is not involved, submit claims for reimbursement for fees on SF 1034 and SF 1034A. Support SF 1034 and SF 1034A with—

- (1) The original receipt or the endorsed cancelled personal check, or copy, for the fee paid by the EN person.
- (2) A copy of the written authorization (see para 14–10, above).

Chapter 15

Affiliation Policy and Procedures

15–1. General

This chapter—

a. Describes the AMEDD's overall affiliation of non-Federal educational institutions with The Army Medical Facilities Program.

b. Sets policies, procedures, and responsibilities for establishing and operating education and training programs in



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5100

REPLY TO
ATTENTION OF

MCMR-UWZ-E

14 December 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Commander's Open Door Policy (Policy #1)

1. I will maintain an open door policy for the soldiers assigned to the Walter Reed Army Institute of Research. I will make myself available to provide guidance, assistance, counseling, and referrals concerning any soldier needs. I recommend that soldiers use their established chain-of-command and NCO Support Channel for resolution of any problems or concerns. However, if they cannot help resolve the concerns, I will.
2. Appointments for assistance can be arranged during duty hours through the orderly room, (301) 319-9390. Anyone requiring immediate assistance during non-duty hours, weekends, or holidays may contact me or the First Sergeant through the WRAIR SDNCO (301) 672-3014.
3. Remember, no problem justifies going AWOL or committing an irrational act. If you have a problem, talk to someone in your chain-of-command or to me. We care about you and want to protect your future.
4. This memorandum supersedes all prior open door policy letters.

//ORIGINAL SIGNED//
MARA KREISHMAN-DEITRICK
CPT, MS
Commanding

DISTRIBUTION:

A&B



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5100

MCMR-UWZ-E

14 December 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Sexual Harassment Policy (Policy #2)

1. Sexual Harassment will not be practiced, condoned, or tolerated within the Headquarters Company, WRAIR. Sexual Harassment includes unwelcome sexual advances, requests for sexual favors, and any other verbal or physical conduct of a sexual nature when:

a. Submission of such conduct is made either explicitly or implicitly in terms or conditions of an individual's duty.

b. Submission to or rejection of such conduct by an individual is used as the basis for duty decisions affecting that individual.

c. Such conduct has the purpose or effect of interfering with an individual's duty performance or creating an intimidating, hostile, or offensive work environment.

2. All soldiers are expected to be professional in their conduct with other personnel. Should you witness or be the victim of sexual harassment, report it to the chain of command, the Provost Marshall's Office, the Inspector General's Office, the Housing Referral Office, the Equal Opportunity Staff, or the Chaplain.

3. This policy will be posted on the Company Bulletin Board until superseded.

//ORIGINAL SIGNED//

MARA KREISHMAN-DEITRICK
CPT, MS
Commanding

DISTRIBUTION:

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DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5100

MCMR-UWZ-E (600-20)

14 December 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Equal Opportunity Policy (Policy # 12)

1. IAW AR 600-20, Chapter 6, the Equal Opportunity Program provides for the just treatment of everyone. By treating our soldiers, civilians, and family members with dignity and respect, we will improve mission effectiveness, cohesion, and readiness. Every member of the command will provide equal opportunity and fair treatment for military personnel, family members, and Department of the Defense civilians without regard to race, color, religion, gender, and national origin. We will abide by this standard in the working, living, and recreational environments, both on and off post, and during both duty and non-duty hours. We cannot and will not tolerate any discrimination in this command.
2. All members of this command will contribute to the essential mission of promoting a positive human relation's atmosphere within the Walter Reed Army Institute of Research and its subordinate units. We will afford all soldiers an equal opportunity to progress and contribute to the advancement of the overall performance of their unit. We must guarantee that our equal opportunity program remains a fundamental part of our vision.
3. The chain of command is responsible for resolving complaints of unlawful discrimination at the lowest level. Complaints will be rapidly and completely investigated. Offenders, and those who falsely accuse others of discriminative practices, will be dealt with decisively. I encourage anyone with a complaint or problem to use their chain of command, however, if you discern that it is a sensitive situation or that the chain of command would be unable to resolve the problem, bring the matter directly to the WRAIR Equal Opportunity Representative, the Company 1SG or me.

//ORIGINAL SIGNED//
MARA KREISHMAN-DEITRICK
CPT, MS
Commanding

DISTRIBUTION:
A&B



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5100

MCMR-UWZ-E (600-20)

27 December 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Equal Opportunity Complaint Processing Procedures (Policy # 13)

1. **Applicability.** This policy statement applies to all Department of the Army (DA) military personnel, civilian employees, and family members of this command.
2. **WHO MAY FILE:** Soldiers and their family members have the right to file complaints of discrimination and/or reprisal if they believe they have been discriminated against because of race, color, religion, gender, or national origin.
3. **WHERE AND HOW TO FILE:** Individuals have the choice to file informal or formal complaints. To file an informal complaint individuals must first attempt resolution by speaking to the offender and providing the chain of command an opportunity to resolve the issue. Although using the chain of command is strongly encouraged, it will not serve as the only channel available to the complainant. Alternate channels are listed in AR 600-20 for soldiers. Civilians are not subject to discipline under this regulation. They are governed by the provisions of AR 690-600. If the complaint cannot be resolved informally, individuals have the option to file formally. Formal complaints will be filed in writing on a DA Form 7279-R and processed IAW AR 600-20. Commissioned officers and Commanders are authorized to administer the oath for EO Complaints. If the complaint is against the commander or members of the Chain of Command, it will be directed to a higher echelon commander in the individual's chain or the Installation Equal Opportunity Office.

//ORIGINAL SIGNED//
MARA KREISHMAN-DEITRICK
CPT, MS
Commanding

DISTRIBUTION:
A&B



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910

REPLY TO
ATTENTION OF
MCMR-UWZ-E

19 September 2008

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Leave and Pass Policy Procedure -- Policy Memorandum #15

1. Purpose: To establish procedures governing the granting of leaves and passes to Soldiers of the WRAIR Headquarters Company.
2. References: AR 600-8-10, Leaves and Passes; AR 385-10, Army Safety Program
3. All Soldiers are encouraged to take leave throughout the year to improve morale and prevent loss of accrued leave.
4. Procedures: Requestors will route their electronic leave/pass request (eDA Form-31) through their supervisory chain (as described below) to the Headquarters Company Commander/1SG for final approval:
 - a. Immediate Supervisor
 - b. Division NCOIC (Inform Division Director)
 - c. Training NCO (SSG Allen and cc: SPC Green)
 - d. HHC Commander (CPT Smith)
 - e. WRAIR Commander (COL Kester) (OCONUS leave/ leave in excess of 30 days/ PTDY),
 - f. Finance Officer, Mr. Cartér
 - g. Soldier (w/ control number)

Once the Division NCOIC has received the eDA Form-31 of the requestor the NCOIC will ensure:

- a. **The eDA Form-31 is routed to the Orderly Room NLT three working days prior to the start of the leave, pass or TDY date.**
- b. The Remarks Section (Block #17 of the eDA Form-31) must include the following statement **"WRAIR SDNCO (301) 672-3014"** and the name of your Division for tracking purposes.
- c. The requesting Soldier has accumulated enough leave for the leave requested.
- d. The requesting Soldiers' Individual Medical Readiness (IMR) is in a 'green' status as reflected in MODS for FMR. If an individual soldier's IMR status is "amber" or "red" due to mitigating circumstances, e.g. Soldier has a temporary profile, the Soldier will be allowed to go on leave.
- e. The requesting Soldier has completed all mandatory training.

f. All Leaves and Passes not adhering to this policy will be returned to the Soldier's NCOIC without digital signature. (Exceptions will be made on a case-by-case basis).

5. Signatory Authority: The Commander of WRAIR will approve all requests for Permissive TDY, OCONUS Leave, and ordinary leave in excess of 30 days. **The Headquarters Company Commander will approve all passes, regular CONUS leave, transitional leave, emergency leave, and convalescent leave less than 30 days.** The HQ Company Staff Duty NCO may sign emergency leave requests after normal duty hours after contacting the 1SG or Company Commander in their absence.

6. The Signature Blocks for paper copies (only if electronic form is not available) that will be used in Block 13 on the DA-31, are as follows

- a. **Kent E. Kester, COL, MC, CDR** (for PTDY, OCONUS leave, ordinary leave greater than 30 days)
- b. **Anton C. Smith, CPT, MS, HQCO, CDR** (for regular CONUS leave, PCS leave, transitional leave, convalescent leave, emergency leave 30 days or less, and all regular mileage/special passes)

7. **All Soldiers must have a copy of their approved leave/pass in their possession before departing on leave. An approved leave form is one where the supervisor and commanders have signed and a control number is present in Block 1 of the DA Form 31.** An approved copy will be returned to the respective Division through distribution. If leave/pass dates change, the Soldier will notify the HQ CO staff to ensure that the leave is charged properly. After duty hours, the Soldier will contact the Staff Duty NCO (301) 672-3014 for leave changes and on the next working day contact the HHC Orderly Room to verify the accuracy of their requested leave.

8. Leave: All leaves are chargeable with the exception of convalescent leave and permissive temporary duty (PTDY).

a. Emergency Leave. Soldiers may request emergency leave with or without American Red Cross verification. Most Soldiers are mature and responsible individuals whose need for emergency leave can be considered on its own merits. Emergency leave will take precedence over all other personnel actions to ensure timely departure of the Soldier. If after duty hours, the Soldier must contact both the Staff Duty NCO and their Division NCOIC. The Division NCOIC will electronically review and forward the eDA Form-31 through the proper personnel as stated above.

b. Advanced Leave. Advanced leave will be approved only after ensuring the Soldier has sufficient time left in the Service to restore the amount of accrued leave to zero balance.

c. Leave Extensions. A Soldier will request leave extensions through their supervisory chain to the appropriate Commander for approval. Upon approval of a leave extension, the HQs

company staff will the Finance Officer is given the following information in order to update the original leave request: Soldier's name, new return date, and number of days leave extended.

d. Transitional Leave (Formerly called Terminal Leave). Transitional leave is chargeable leave granted when a Soldier begins their transition (ETS/Retirement) from the service. The transitional leave period is authorized for the full amount of a Soldier's leave balance **When requesting transitional leave, a copy of the requestor's most recent LES and a copy of their separation orders must be attached to the electronic DA-31.**

e. Permissive Temporary Duty (PTDY). PTDY may be authorized for house hunting incident to a PCS move CONUS or OCONUS. Not more than 10 days will be authorized. Service members who voluntarily separate from the military as a result of expiration of term of service (ETS) are not eligible for PTDY. Service members who are involuntarily separated from the service (except under dishonorable conditions) are authorized to request ten (10) days PTDY. Service members retiring from the service can request up to twenty (20) days PTDY.

f. OCONUS Leave. In order to ensure that all required documents are included in OCONUS leave requests, **all requests for OCONUS leave (including leave in conjunction with official travel) should be initiated through Mr. Frank Cartér (301-319-9329) a minimum of 45-60 days prior to travel.** Any OCONUS travel request that arrives at MRMC for approval less than 30 days prior to travel will require a written justification of lateness.

9. Passes (regular/special/mileage): A pass is an authorized absence from post or place of duty. Passes are not a right, but a privilege to be awarded to deserving Soldiers. Passes are valid for four months from the day they are awarded. Non-duty periods of absence, other than the established/normal duty hours, are considered a pass period. Passes that have been awarded to a Soldier may be suspended or withdrawn by the Company Commander for reasons such as poor duty performance or misconduct, especially when the Soldier has an active flag. For all regular and special pass requests, a copy of a memorandum signed by the Company Commander authorizing the pass must be submitted as an attachment with the DA-31.

a. Regular 3-day Pass: A regular 3-day pass is a short, nonchargeable absence from post or place of duty that is issued by the Commander to soldiers whose performance of duty and conduct merit recognition. A regular pass may be granted together with leave if the pass begins and ends on post, at the duty location, or at the location from which the Soldier normally commutes to duty before the pass begins. A regular pass shall not be used in conjunction with another pass without a duty day in between the absences. **If a Soldier takes a regular pass in conjunction with leave, the following statement must be initialed by the Soldier and included in block 17 of the DA 31, "Soldier will begin and end leave at place of commute IAW AR 600-8-10, Paragraph 5-27h."**

b. Special Passes: Special passes may be granted as special recognition for exceptional performance of duty, as compensatory time off, etc. Passes are not a right, but a privilege to be awarded to deserving Soldiers. All requests for special passes must be submitted on DA Form 31 with the supporting documentation that states why the pass was awarded. There are two kinds of special passes: three-day and four-day. Special passes can be used in conjunction with ordinary leave without a normal duty day in between absences, provided the Soldier is at the duty station or local residence at the beginning and end of the leave and pass. Special passes can be used in

conjunction with TDY. A special pass may not be used in conjunction with a regular pass, another special pass or leave.

(1) A 3-day special pass period must include at least one duty day. The period normally begins at the end of the normal duty day on a given day and ends with the start of normal duty on the 4th day. Normally this period is Tuesday, Wednesday and Thursday, depending on unit duty requirements. (For example, a Soldier may depart at the end of the duty day on Monday evening, and must return at the start of normal duty day on Friday). Due to the nature of the duty requirements of this Institute in which most Soldiers do not work on “shifts”, the 3-Day passes will only be authorized to Soldiers whose duties involve frequent weekend shifts. When such situation applies, a memorandum from the Soldier’s supervisor must be attached to the eDA Form-31.

(2) A 4-day special pass period must include at least two consecutive non-duty days. For example, a Soldier may depart on a 4-day pass on Thursday evening after duty day and must return prior to the start of normal duty day on Tuesday.

c. Mileage passes: On weekends, a mileage pass is required if a Soldier wishes to travel by personally owned vehicle (POV) or commercial bus to a destination to which the driving distance is between 360 and 600 miles from their residence. Leave will be required for travel by POV or bus if the traveling distance is greater than 600 miles one way, or for other commercial travel (Plane or Train). A Soldier is also authorized to use a pass (3-day or 4-day) to travel to a destination to which the driving distance is greater than 600 miles without being charged annual leave, provided the mode of transportation is by train, bus, or commercial airplane. **A statement indicating commercial mode of transportation should be included in the remarks section of the DA31.** It is each Soldier’s responsibility to be present for duty after the mileage pass period ends. In the event of inclement weather, terrorist attack, or any other circumstance that prevents the Soldier from reporting to duty, the pass period and any additional missed duty days will be converted to chargeable leave.

10. Mandatory safety requirements: When traveling by POV, to include automobiles and motorcycles, a pre-trip risk assessment (U.S. Army Combat Readiness Center POV Risk Assessment Tool (TRiPS), <https://crc.army.mil/home/>), safety checklist (Appendix A) and POV inspection checklist (Appendix B) must be completed and as an attachment to the DA-31. Checklists that are equivalent to Appendices A&B can also be downloaded by visiting the website of the Army Combat Readiness Center, <https://crc.army.mil/home/>.

When traveling by Air, the only requirement is an itinerary to and from your leave location.

All safety required documents will be forwarded with the leave/pass form as an attachment. Leave/ pass requests missing those documents will not be approved.

11. Two templates of DA-31 have been provided in Appendices C and D as a reference for the preparation of your leave form.

102. The POC for this memorandum is the undersigned at 301-319-9362, anton.c.smith@amedd.army.mil.

// ORIGINAL SIGNED//
ANTON C. SMITH
CPT, MS
Commanding

REQUEST AND AUTHORITY FOR LEAVE				1. CONTROL NUMBER	
This form is subject to the Privacy Act of 1974. For use of this form, see AR 600-8-10. The proponent agency is DCS, G-1. (See instructions on reverse.)					
PART I					
2. NAME (Last, First, Middle Initial)		3. SSN		4. RANK	
Green William L		123-45-6789		SPC	
5. DATE		20080923			
6. LEAVE ADDRESS (Street, City, State, ZIP Code and Phone No.)		7. TYPE OF LEAVE		8. ORGN, STATION, AND PHONE NO.	
2966-B Mcgee Ct. Ft. Meade, MD 20755 210-705-4827		<input checked="" type="checkbox"/> ORDINARY <input type="checkbox"/> PERMISSIVE TDY <input type="checkbox"/> EMERGENCY <input type="checkbox"/> OTHER		WRAIR 503 Robert Grant Ave. Silver Spring, MD 20910 Ext. 7388	
9. NUMBER DAYS LEAVE					
a. ACCRUED	b. REQUESTED	c. ADVANCED	d. EXCESS	10. DATES	
45	35	NA	NA	a. FROM	b. TO
				20081013	20081116
11. SIGNATURE OF REQUESTOR		12. SUPERVISOR RECOMMENDATION/SIGNATURE		13. SIGNATURE AND TITLE OF APPROVING AUTHORITY	
Electronically sign		<input checked="" type="checkbox"/> APPROVAL <input type="checkbox"/> DISAPPROVAL		Electronically sign	
14. DEPARTURE					
a. DATE	b. TIME	c. NAME/TITLE/SIGNATURE OF DEPARTURE AUTHORITY			
15. EXTENSION					
a. NUMBER DAYS	b. DATE APPROVED	c. NAME/TITLE/SIGNATURE OF APPROVAL AUTHORITY			
16. RETURN					
a. DATE	b. TIME	c. NAME/TITLE/SIGNATURE OF RETURN AUTHORITY			
17. REMARKS					
WRAIR SDNCO (301) 672-3014 Division - HQCO					
Chargeable leave is from _____ to _____					
PART II - EMERGENCY LEAVE TRANSPORTATION AND TRAVEL					
18. You are authorized to proceed on official travel in connection with emergency leave and upon completion of your leave and travel will return to home station (or location) designated by military orders. You are directed to report to the Aerial Port of Embarkation (APOE) for onward movement to the authorized international airport designated in your travel documents. All additional travel is chargeable to leave. Do not depart the installation without reservations or tickets for authorized space required transportation. File a no-pay travel voucher with a copy of your travel documents or boarding pass within 5 working days after your return. Submit request for leave extension to your commander. The American Red Cross can assist you in notifying your commander of your request for extension of leave.					
19. INSTRUCTIONS FOR SCHEDULING RETURN TRANSPORTATION:					
For return military travel reservations in CONUS call the MAC Passenger Reservation Center (PRC): Should you require other assistance call PAP:					
20. DEPARTED UNIT	21. ARRIVED APOD	22. ARRIVED APOE (return only)	23. ARRIVED HOME UNIT		
PART III - DEPENDENT TRAVEL AUTHORIZATION					
24. (Space available or required cash reimbursable) <input type="checkbox"/> ONE WAY <input type="checkbox"/> ROUND TRIP					
25. (Space required) TRANSPORTATION AUTHORIZED FOR DEPENDENTS LISTED IN BLOCK NO. 25					
DEPENDENT INFORMATION					
a. DEPENDENTS (Last name, First, MI)	b. RELATIONSHIP	c. DATES OF BIRTH (Children)	d. PASSPORT NUMBER		
PART IV - AUTHENTICATION FOR TRAVEL AUTHORIZATION					
26. DESIGNATION AND LOCATION OF HEADQUARTERS			27. ACCOUNTING CITATION		
28. DATE ISSUED	29. TRAVEL ORDER NUMBER	30. ORDER AUTHORIZING OFFICIAL (Title and signature) OR AUTHENTICATION			

REQUEST AND AUTHORITY FOR LEAVE This form is subject to the Privacy Act of 1974. For use of this form, see AR 600-8-10. The proponent agency is DCS, G-1. (See instructions on reverse.)						1. CONTROL NUMBER			
PART I									
2. NAME (Last, First, Middle Initial) Green William L			3. SSN 123-45-6789		4. RANK SPC		5. DATE 20080923		
6. LEAVE ADDRESS (Street, City, State, ZIP Code and Phone No.) 2966-B Mcgee Ct. Ft. Meade, MD 20755 210-705-4827				7. TYPE OF LEAVE <input checked="" type="checkbox"/> ORDINARY <input type="checkbox"/> EMERGENCY <input type="checkbox"/> PERMISSIVE TDY <input type="checkbox"/> OTHER		8. ORGN, STATION, AND PHONE NO. WRAIR 503 Robert Grant Ave. Silver Spring, MD 20910 Ext. 7388			
9. NUMBER DAYS LEAVE						10. DATES			
a. ACCRUED 45		b. REQUESTED 15		c. ADVANCED NA		d. EXCESS NA		a. FROM 20081013	b. TO 20081027
11. SIGNATURE OF REQUESTOR <i>Electronically Sign</i>			12. SUPERVISOR RECOMMENDATION/SIGNATURE <input checked="" type="checkbox"/> APPROVAL <input checked="" type="checkbox"/> DISAPPROVAL <i>Electronically Sign</i>			13. SIGNATURE AND TITLE OF APPROVING AUTHORITY <i>Electronically Sign</i>			
14. DEPARTURE									
a. DATE		b. TIME		c. NAME/TITLE/SIGNATURE OF DEPARTURE AUTHORITY					
15. EXTENSION									
a. NUMBER DAYS		b. DATE APPROVED		c. NAME/TITLE/SIGNATURE OF APPROVAL AUTHORITY					
16. RETURN									
a. DATE		b. TIME		c. NAME/TITLE/SIGNATURE OF RETURN AUTHORITY					
17. REMARKS WRAIR SDNCO (301) 672-3014 Division - HQCO Chargeable leave is from _____ to _____									
PART II - EMERGENCY LEAVE TRANSPORTATION AND TRAVEL									
18. You are authorized to proceed on official travel in connection with emergency leave and upon completion of your leave and travel will return to home station (or location) designated by military orders. You are directed to report to the Aerial Port of Embarkation (APOE) for onward movement to the authorized international airport designated in your travel documents. All additional travel is chargeable to leave. Do not depart the installation without reservations or tickets for authorized space required transportation. File a no-pay travel voucher with a copy of your travel documents or boarding pass within 5 working days after your return. Submit request for leave extension to your commander. The American Red Cross can assist you in notifying your commander of your request for extension of leave.									
19. INSTRUCTIONS FOR SCHEDULING RETURN TRANSPORTATION: For return military travel reservations in CONUS call the MAC Passenger Reservation Center (PRC). Should you require other assistance call P.A.P:									
20. DEPARTED UNIT		21. ARRIVED APOD		22. ARRIVED APOE (return only)		23. ARRIVED HOME UNIT			
PART III - DEPENDENT TRAVEL AUTHORIZATION									
24. <input type="checkbox"/> (Space available or required cash reimbursable) <input type="checkbox"/> ONE WAY <input type="checkbox"/> ROUND TRIP <input type="checkbox"/> (Space required) TRANSPORTATION AUTHORIZED FOR DEPENDENTS LISTED IN BLOCK NO. 25									
DEPENDENT INFORMATION									
a. DEPENDENTS (Last name, First, MI)		b. RELATIONSHIP		c. DATES OF BIRTH (Children)		d. PASSPORT NUMBER			
PART IV - AUTHENTICATION FOR TRAVEL AUTHORIZATION									
26. DESIGNATION AND LOCATION OF HEADQUARTERS				27. ACCOUNTING CITATION					
28. DATE ISSUED		29. TRAVEL ORDER NUMBER		30. ORDER AUTHORIZING OFFICIAL (Title and signature) OR AUTHENTICATION					



**Walter Reed Army Institute of Research and Uniformed Services University of the Health Sciences
Clinical Pharmacology Fellowship Training Program**

Fellow Research Project Approval Form

INSTRUCTIONS: This form must be completed for all proposed fellow projects. The primary faculty mentor and the Clinical Pharmacology Fellowship Directors must sign the form before a fellow may begin the project. This form does not replace the formal protocol review process.

Fellow Name: _____ Date: _____

Primary Faculty Mentor: _____

Project Title: _____

Project Location(s): _____

Study Question:

Brief Description of the Project: (include background, study design, methods, data sources, final product, cost, funding sources, collaborators, and role of the fellow). Attach additional pages as needed, and a brief timeline for the project to this form.



Fellow Research Project Approval Form

Signature of Mentor: _____

☐ Approved

☐ Disapproved

USUHS Director Signature

Date

WRAIR Director Signature

Date

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 Scott Street
Fort Detrick, Maryland 21702-5012

USAMRMC Regulation
No. 360-1

1 JUN 2006

Public Affairs
SECURITY AND POLICY REVIEW
CLEARANCE OF PROFESSIONAL MANUSCRIPTS AND PRESENTATIONS

Supplementation of this regulation is prohibited without prior approval from Headquarters (HQ), U.S. Army Medical Research and Materiel Command (USAMRMC) Public Affairs (MCMR-ZC-A).

1. **HISTORY.** This regulation supersedes Command Policy 2002-33, 28 Jun 02.
2. **PURPOSE.** This regulation establishes the procedures for clearing for public presentation the professional work products created by USAMRMC personnel who work in any unit or any mission area of the USAMRMC.
3. **REFERENCES.** References are listed in Appendix A.
4. **EXPLANATION OF ABBREVIATIONS AND TERMS.**
 - a. Author's Agency: The unit of assignment of the author (e.g., U.S. Army Medical Research Institute of Infectious Diseases or U.S. Army Health Facility Planning Agency).
 - b. Professional Work Products: Manuscripts, abstracts, articles, speeches, presentations, charts and graphs, data sources, interviews, photographs, videos, or audio recordings produced while working for the USAMRMC.
 - c. Public Presentation: Presentation of a talk, slide show, or poster at a professional or other public meeting that is open to anyone with an interest in the topic. A manuscript or article published in an accessible professional or commercial journal, periodical, book or newspaper, or published on an unrestricted web site.
 - d. Technical Managers: An editorial review committee or individuals with appropriate credentials, appointed by the commander/director of the unit, and given the authority to clear professional work for that unit.
5. **APPLICABILITY.** This regulation applies to HQ, USAMRMC and all of the Command's subordinate units and laboratories.

6. RESPONSIBILITIES.

a. The Public Affairs Office (PAO) for the USAMRMC will be the sole point of entry to initiate clearance reviews for professional work products that require higher-level review, as described in paragraph 8a (1-4), below.

b. Professional work prepared by personnel assigned to the Headquarters, USAMRMC, will be reviewed and approved by the HQs' senior functional manager (e.g., Research Area Director or Deputy) in the subject matter area.

c. Technical managers at the author's agency must review and validate the content of professional work and approve it locally for publication, ensuring compliance with the regulations at Appendix A.

(1) The laboratory/unit will ensure that each presentation and each paper submitted for publication carries the appropriate disclaimer (for example, "Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.").

(2) Papers or presentations describing research involving human subjects will identify the specific human use protocol associated with the research. Documentation of the Human Use Review Committee and/or Human Subjects Research Review Board approval or determination of exempt status will be submitted with the paper or presentation that is to be reviewed.

(3) All professional work (written, audio, and visual) regarding specific techniques involving animals should be acceptable to a wide audience, including lay as well as scientific readers. Other scientists are the intended audience for most scientific publications and presentations. However, once published or posted on the internet, this information becomes widely available. Publications and presentations describing the use of animals involving research development, test and evaluation; clinical investigation; or instruction will include a statement of compliance with the Animal Welfare Act and implementing Animal Welfare Regulations, when applicable. Publications and presentations should also include a statement of adherence to the principles noted in "The Guide for the Care and Use of Laboratory Animals." Laboratories will ensure that a laboratory animal veterinarian reviews professional work involving use of laboratory animals.

(4) Professional work that has been previously cleared will need to be cleared again when the information is being presented to a new audience. Further, if there are substantial changes in the submitted work that adds new information or significantly changes the conclusion, the author will resubmit the material to the unit's clearance authority to determine if a new clearance review is required.

d. Questions regarding intellectual property issues, including patents-related matters, relative to papers and presentations will be referred to the Command's Staff Judge Advocate at HQ, USAMRMC. If personally appearing to make the presentation at a conference or non-

governmental meeting, supervisory approval and an ethics counselor's legal review must be obtained.

e. Authors of scientific manuscripts and presentations are asked to consider operational security guidance before they begin writing. Operational Security guidance is summarized at Appendix C. The USAMRMC DCSOPS routinely provides operational security training when requested by units.

f. The USAMRMC Chief of Staff will serve as the appeal authority on whether professional work products meet operational security guidelines. The Commanding General will make the final decision if necessary.

g. Manuscripts, posters and presentations on OTSG-sponsored investigational new products will be coordinated before submission for clearance with the appropriate program management and regulatory affairs offices at the US Army Medical Materiel Development Activity.

7. POLICIES.

a. The USAMRMC is a prolific medical research organization. Timely publication or presentation of unclassified scientific and technical information developed in the Command's laboratories is encouraged.

b. Professional work published or presented by USAMRMC personnel in the course of their official duties is considered official information. Release of such official information in manuscripts, abstracts, articles, speeches, presentations, charts and graphs, data sources, interviews, photographs, videos, or audio recordings is regulated by the references in Appendix A.

c. Clearance of professional work at the local level is highly encouraged and, in most cases, can be accomplished at that level. See paragraph 8a (1-4) for exceptions.

8. PROCEDURES.

a. In accordance with Army Regulation 360-1, papers and presentations may be cleared locally when the scope and content of the article, paper or presentation, is entirely within the mission area of the author's unit. However, higher-level clearance (i.e., by HQ, USAMRMC, U.S. Army Medical Command (USAMEDCOM) or Department of the Army (DA)) is required for the following types of professional work:

(1) Content and scope that goes beyond the responsibility of the author's unit. (For example, a presentation on development of a product that involves two units of the command and a non-DOD federal agency.)

(2) Presentations at meetings that take place overseas.

USAMRMC Regulation 360-1

(3) Papers or presentations that can be considered high visibility, politically sensitive, or likely to generate media interest. (For example, a study indicating a growing number of soldiers seek mental health care when they return from deployment to a combat zone.)

(4) Papers or presentations that deal with chemical and biological defense.

b. When papers or presentations meet the criteria for higher-level review described above, the following procedures will apply and are outlined in Appendix B:

(1) After papers or presentations are cleared through the unit's review process, the unit will send a copy of the paper or presentation via e-mail to the USAMRMC PAO with sufficient time, typically 30 days, to accomplish a clearance review. (30 days lead time is required if Department of Army level review for clearance is required. Most clearance reviews do not take 30 days.)

(2) For papers, the sender must note where the author anticipates it will be published and when it will appear in print. Abstracts for journal articles, as well as full articles, must undergo the clearance review process.

(3) For presentations, the sender must provide the name, date and location of the meeting at which the presentation will occur. Foreign nationals will be assumed to be in the audience at open scientific meetings in the U.S.

(4) Once the paper or presentation is received at the USAMRMC PAO, that office will initiate a clearance review that includes:

(a) Public affairs assessment of whether the work product will attract media attention, and what prior coordination with other agencies is warranted.

(b) OPSEC. Appendix C provides common OPSEC concerns for professional work products created by researchers from USAMRMC labs and units.

(c) International Affairs and Biological Arms Control Treaty Office, if a presentation is being given overseas or could have Department of Commerce export license restrictions.

(d) Higher-level review by USAMEDCOM and DA, if necessary. (AR 360-1 lists presentation topics that require DA or OSD clearance. Some papers and presentations on chemical and biological defense research require DA clearance.

(5) Every effort will be made to ensure the clearance process is a timely one. However, if reviewers have concerns or questions about the information in the paper or presentation, the USAMRMC PAO will send those concerns back to the sender of the original e-mail for resolution. No clearances will be granted until concerns and questions are resolved and documented by e-mail correspondence.

(6) If a paper is not recommended for clearance because of OPSEC concerns, the author, with unit commander approval, may appeal the decision through the USAMRMC Chief of Staff. If a compromise cannot be reached, the USAMRMC Commanding General will have final decision authority on the appeal. If the appeal is denied, the author must change the material before it is released to the public.

(7) Once the paper or presentation has undergone the complete clearance review process, the PAO will reply to the original e-mail, indicating that clearance has been granted.

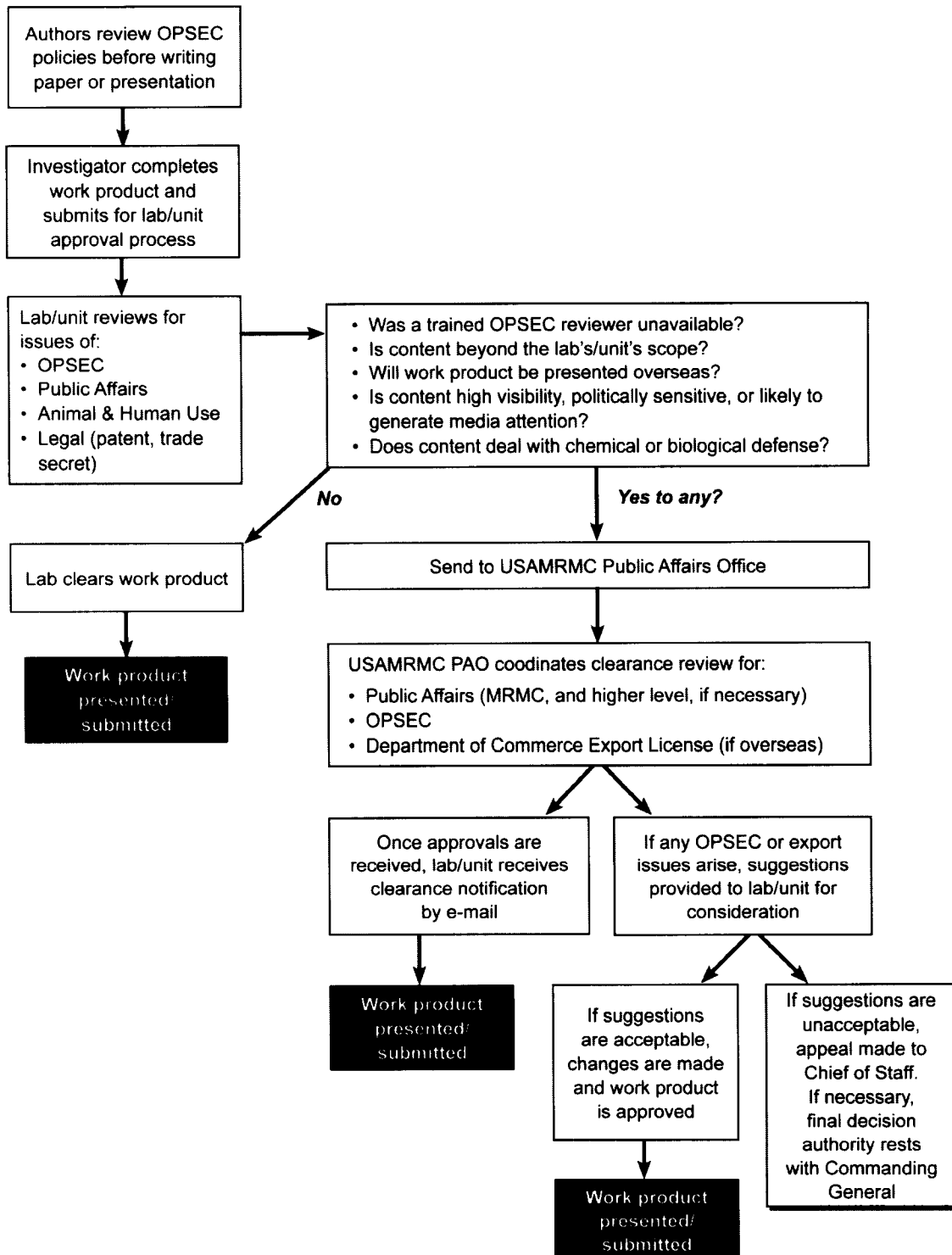
Appendix A

References

1. 7 USC, 2131-2159, Animal Welfare Act, 24 Aug 66, as amended.
2. Guide for the Care and Use of Laboratory Animals, National Research Council, 1996.
3. Title 9, Code of Federal Regulations, Animals and Animal Products, Chapter 1, Subchapter A, Parts 1-4, "Animal Welfare Regulations."
4. DOD Directive 3216.1, Use of Laboratory Animals in DOD Programs, 17 Apr 95.
5. DOD Directive 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 25 Mar 2002.
6. DOD Directive 5230.9, Clearance of Public Information for Public Release, 9 Apr 96 and incorporating change 1, 15 Jul 99. Certified current as of 21 Nov 03.
7. AR 70-14, Publication and Reprints of Articles in Professional Journals, 13 Nov 85.
8. AR 40-33, The Care and Use of Laboratory Animals in DOD Programs, 16 Feb 05.
9. AR 70-31, Standards for Technical Reporting, 10 Mar 86.
10. AR 70-25, Use of Volunteers as Subjects of Research, 25 Jan 1990
11. AR 360-1, Army Public Affairs Program, 15 Sep 00.
12. AR 530-1, Operations Security, 27 Sep 05.
13. OTSG/MEDCOM Policy Memorandum 05-002, Clearance Procedures for the Public Release of Official Information about the Army Medical Department (AMEDD) Obtained Because of Official Position, 24 Feb 05.
14. OTSG/MEDCOM Policy Memorandum 5-018, Release of Actionable Medical Information, 2 Dec 05.

Appendix B

Clearance Review Process



Appendix C

Operational Security

1. The following list, though not all inclusive, provides guidance for operational security concerns that could appear in professional work products created by researchers from USAMRMC labs and units. References listed at the beginning of this document provide more specific guidance. In general, writers should avoid:

- a. Classified or For Official Use Only information.
- b. Linking weapons systems or equipment vulnerabilities to resulting wound patterns. Work products must not include:
 - (1) Specific links between defined wounding methods and the resulting wound patterns;
 - (2) Specific links between injuries sustained while wearing defined personal protective equipment and the resulting wound pattern;
 - (3) Specific links between injuries sustained while in defined vehicles and the resulting wound patterns; and
 - (4) Discussion or specific ballistic agents and the resulting failure of personal protective equipment or vehicles.
- c. Linking casualties or injuries that occurred from specific attacks, located in a specific area, or on a specific date.
- d. Providing units and locations.
- e. Providing casualty rates in relation to deployed troops strengths or compared over time. Other figures such as killed in action, died of wounds or case fatality rate are permissible as long as they do not show a relationship with troop strength or trends over time.
- f. Photos or videos that reveal vulnerabilities of protective equipment for individuals, vehicles or other hardened structures. This also includes physical security measures, such as security checkpoints.
- g. Photos of military wounded that include anything that would conclusively identify a military casualty, i.e. uniforms, tents, etc.
- h. Photos of POWs or any photos that could be misinterpreted by the media, such as photos of female medical personnel caring for male Muslim patients.

i. Disseminating protected health information, as defined by the Health Insurance Portability and Accountability Act, Privacy Act information and exemptions under the Freedom of Information Act.

j. Formulas that include LD50 information, dissipation rates, detection rates for select toxins and agents, etc.

USAMRMC Regulation 360-1

The proponent of this memorandum is the USAMRMC PAO. Users are invited to send comments, suggestions, and recommendations for improvements on Department of the Army Form 2028 (Recommended Changes to Publications and Blank Forms) to Commanding General, U.S. Army Medical Research and Materiel Command (MCMR-ZC-A), 504 Scott Street, Fort Detrick, MD 21702-5012.

FOR THE COMMANDER:

OFFICIAL:

GARRY F. ATKINS
Colonel, MS
Chief of Staff



TANYA M. JUAREZ
CPT, MS
Secretary of the General Staff

DISTRIBUTION:

A

1st Year Courses

FAES- NIH Courses: Statistics for Biomedical Scientists (STAT 500M)

(<http://www.faes.org/>):

- **Registration** Information: Sponsored by NIH and hosted on the NIH campus.
 - Registrars Number: (301) 496-7976
 - Registrars Email: lyonsa@mail.nih.gov
 - Address: One Cloister Court, Building 60, Suite 230, Bethesda, MD 20814
 - All documentation required for registration is available online (click on grad school): the registration card, dates, etc. As the documents receive updated dates according to the specific year, there is no need to pre-print bundles of registration cards with the wrong dates.
- **REGISTRATION DEADLINES:**
 - To register for the Fall semester, you must complete early registration by the first week of August.
 - After pre-registration, they offer walk in registrations on specific dates at the registrars office.
- **Cost:** \$345, no course should be paid out of pocket, unless it is an unauthorized course.
- **Course Days:** This course is typically on a Tuesday or Wednesday evening.
- **Details:** A grade and a CME certificate are awarded for each semester upon completion. A copy of the certificate must be handed to the Educational Specialist.
- **Course Objective:** The objective of this course is to provide an overview of statistics for biomedical research workers and clinicians who are interested in interpretation of the results of statistical analysis. A series of integrated lectures on analysis and interpretation of medical research data. Emphasis is on ideas and understanding rather than mechanics. Topics covered in the first semester include the foundation of statistical logic and the most commonly encountered statistical procedures in medical research. The second semester expands on the material covered in the first semester by looking at assumptions, extensions, and alternatives for common procedures. STAT 500M is a full-year course. Material covered in the first semester is necessary to satisfactorily undertake the second semester. Attendance for the second semester if you would like to attend, can be requested through the Program Directors.

Principles of Clinical Pharmacology (NIH):

- **Registration Information:**
 - Contact Person: Donna L. Shields (DShields@mail.cc.nih.gov), Clinical Pharmacology Coordinator
 - Contact Information: (301) 435-6618
 - Address: Office of Clinical Research Training & Medical Education, NIH Clinical Center
 - Can be registered online.
- **Website:** <http://www.cc.nih.gov/training/training/principles.html>
 - Course schedule, times, locations, etc. can also be viewed online at the above site
- **REGISTRATION DEADLINES:**
 - Register in August.
- **Cost:** Free course
- **Course Months:** Runs from first week of September through end of April.
- **Course Time:** From 1830 to 1945.
- **Course Location:** NIH Center, Lipsett Auditorium, Building 10 or via Video Conference at WRAIR, Room 1w76 if WRAIR is given off-sight privilege
- **Details:** A certificate of completion is issued based on 80% or greater attendance. Upon completion, a copy of the certificate must be submitted to the Educational Specialist.

Good Clinical Practices:

- **Details:** Generally a one to three day course that covers: ethics/issues, regulatory requirements, informed consent, etc.
- **Cost:** Generally between \$150.00-\$180.00
- **Website:** Fellows can do a search for locations offering GCP courses. The following sites offer classes at various times and prices:
 - WRAIR has in the past scheduled a GCP course for attendance.
 - The Office of Regulatory Affairs of USAMRMC (<https://mrmc.amedd.army.mil/usammda/index.cfm?page=raft>) at Ft. Detrick typically offers a series of GCP Courses: GCP, Basic; GCP Refresher, and Applied GCP. They also offer Good Laboratory Practices and Good Manufacturing Practices.
 - <http://www.peri.org/> and search for Good Clinical Practices
 - Cost: approximately \$1,400.00 (look for the government rate)
 - 3 Day Program
 - Contact: (703) 276-0178
 - Register: On-Line or Mail/Fax

Ethics: CITI Human Participant Protections (online):

- **Website** for NIH: www.citiprogram.org (take full module):
 - Registration site asks if you want a certificate only or certificate and a credit, per prior Director, COL Ralph Brueckner, select option #3 (no charge-NIH site).
- **NOTE:** This course must be completed prior to the Fellow's participation in clinical studies activities.

USUHS Medical Student Pharmacology Course

(physician Fellows: Audit)

(non-physician Fellows: Register – this is dependent on a case by case basis)

- **Registration:**
 - Class administered by the USUHS Department of Pharmacology. Please contact Mr. Alonzo Cruder (301-295-3223) for details.
- **REGISTRATION DEADLINES:**
 - Contact Mr. Cruder by the end of October regarding.
- **Course Months:** Runs from January through April.
- **Course Location:** USUHS
- **Details:** This is an audit only course; however, for certain individuals without a strong pharmacology background, full participation in this course will be required. Fellows must take the course examinations and make a self-assessment of any areas where additional study is warranted. Please contact the Educational Specialist for the Exams (4 total). Once the exam is complete, the Fellow contacts the Educational Specialist for the answer sheet to self-grade. Fellows must submit the scored exam (total 4) to the Educational Specialist for their permanent file. If the Fellow was required to register for the Course, each exam/quiz needs to be submitted to the Educational Specialist for their permanent file.
- **Course Description:** The 2009 Course Schedule is available for review further on in the Course Work Info appendix (sleeve 7).

2nd Year Courses

Introduction to the Principles and Practice of Clinical Research (NIH):

- **Registration Information:**
 - Email: od_ipPCR@cc.nih.gov
 - Register online (address below)
- **Website:** <http://www.cc.nih.gov/training/training/ipPCR.html>
 - Site offers course information and registration details, contact information, etc.
- **REGISTRATION DEADLINES:**
 - Register by the end of July or beginning of August.
- **Cost:** Free Course
- **Course Months:** Typically runs from October to February.
- **Course Days:** The course is typically on Monday and Tuesday evenings.
- **Course Time:** From 1700 to 1830.
- **Course Location:** NIH, Lipsett Auditorium, Building 10
- **Details:** A final exam is given (online) and 75% is required for a certificate of completion. Upon completion, a copy of the certificate must be submitted to the Educational Specialist.
- **Course Objectives:**
 - To become familiar with the basic epidemiologic methods involved in clinical research;
 - To be able to discuss the principles involved in the ethics of clinical research, the legal issues involved in clinical research, and the regulations involved in human subjects research, including the role of institutional review boards (IRBs) in clinical research.
 - To become familiar with the principles and issues involved in monitoring patient-oriented research.
 - To be able to discuss the infrastructure required in performing clinical research and have an understanding of the steps involved in developing and funding research studies.

Ethical and Regulatory Aspects of Clinical Research:

- **Registration Information:**
 - Course offered through NIH.
 - Registration is completed by sending the following information to mstallings@cc.nih.gov (Mertis Stallings):
 - First and Last Name
 - Degrees/Credentials (Social Worker, Physician, Psychologist, Nurse, etc.)
 - NIH Badge ID Number
 - NIH Institute
 - Campus Address
 - Work Email Address
 - Work Phone Number
 - Contact Number: (301) 496-2429
- **Website:** <http://www.bioethics.nih.gov/hsr/index.shtml>
 - Offers full details as to course dates, times, location etc.:
- **REGISTRATION DEADLINES:**
 - Register by mid-August
- **Cost:** Free course
- **Course Months:** Typically runs from October through November.
- **Course Days:** The course is typically on Wednesday mornings. It also tends to start in September and end in November.
- **Course Time:** From 0830 to 1130.
- **Course Location:** NIH, Lipsett Auditorium, Building 10
- **Details:** There is a required text. Contact the Educational Specialist to help you acquire it.

- **Course Objectives:**
 - Utilize a systematic framework for evaluating the ethics of a clinical research protocol.
 - Apply appropriate codes, regulations, and other documents governing the ethical conduct of human subject research to their own research.
 - Discuss controversial issues relating to human subject research, including Phase 1 research, randomization, children in research, international research, etc.
 - Identify the critical elements of informed consent and strategies for implementing informed consent for clinical research.
 - Describe the purpose, function, and challenges of IRBs.
 - Appreciate the experience of human subjects who have participated in research protocols.

FDA Rotation:

- COL Ohrt is the point of contact for Fellow involvement in the FDA rotation cycle.
- More information regarding this is under the appendix entitled: FDA
- **REGISTRATION DEADLINES:**
 - Fellows should start making arrangements for this Rotation in July/August of their second year.
- **NOTE:** Must ensure security clearance is up to date prior to the start of the rotation.

Topics in Clinical Trials (Dr. Temple):

- **Registration Information:**
 - Contact Person: Ms. Tiffany Edmonds
 - Contact Email: tiffany.edmonds@fda.hhs.gov
 - Contact Number: (301) 796-3611
- **REGISTRATION DEADLINES:**
 - Register by early December.
- **Cost:** Free course
- **Course Months:** Typically runs from February to June.
- **Course Days:** Days varies.
- **Course Time:** Time varies.
- **Course Location:** Typically held at the Shared Use Building, Room 2047 at the FDA White Oak Campus
- **Details:** Fellows must attend at least 80% of the lectures (8 or more sessions) and complete the final course evaluation, including your name, in order to receive a course completion.
- **Course Objectives:** Clinical trials are conducted to determine if a drug is safe and effective. This course consists of a series of lectures given by regulatory scientist within the FDA who discuss topics such as the interpretation of regulatory law related to clinical trials, clinical trials and meta-analysis, drug dose response, alternative clinical study design, the review of clinical safety data and surrogate markers. Case examples are used to illustrate the relevance of these topics to the review of a new drug application (NDA). There is time for discussion of these cases and topics allowed at the end of the lectures. The goal of this course is for the participant to gain a better understanding of the FDA review process of clinical trials of new drugs.
 - Describe law and regulations that relate to new drug development and the drug approval process in the US.
 - Discuss the design and interpretation of well-controlled clinical trials for new drug development.
 - Detect flawed and inappropriate clinical trial designs.
 - Identify clinical trial design options used to assess the effectiveness of a drug.
 - Discuss approaches to evaluate clinical trials that assess the safety and effectiveness of a new drug.
- **Course Description:** The 2009 Course Schedule is available for review further on in the Course Work Info appendix (sleeve 8).

Required Courses in both the 1st and 2nd Year

USUHS Medical Student Clinical Pharmacology Course (3rd and 4th year medical students):

- This is primarily a **teaching** activity for the Fellows.
- **Registration Information:**
 - Class taught by Dr. Lou Cantilena. Please contact Ms. Annette Cunningham (301-295-3239) for details.
- **Course Months:** In December of both years of the Fellowship.
- **Course Location:** USUHS in the Multi-Disciplinary Laboratories and various lecture halls.
- **Details:** Physician Fellows are expected to assist with the preparation of course materials and assist or lead with the instruction of a small group discussion with the students. Non-physician Fellows will be paired each year with a Physician Fellow/staff member. In the second year, it is expected that the non-physician Fellow will prepare the small group discussions under the tutelage of the staff member.
- **Course Description:** The 2009 Clinical Pharmacology Intersession Packet of Information is available for further review further in the Course Work Info appendix (sleeve 9).

Journal Club:

- This is primarily a **teaching** activity for the Fellows.
- Each Fellow must lead journal club at least once in each year of their fellowship.
- Under the supervision of a faculty member, some of the scheduled lectures will be conducted as a journal club, where the Fellows will present important articles in clinical pharmacology and learn to critically evaluate a research paper. If needed, journal clubs will be scheduled around the time of the lecture series.

Clinical Consultation Service/Morning Report/Clinical Pharmacology and Medical Toxicology Educational Consultation Conference:

- Fellows are expected to be on-call for monthly rotations on the Clinical Pharmacology Clinical Consultation Service.
- The schedule should be prepared by the second year Fellows at the beginning of each year, approved by the Program Directors, and be provided to the USUHS and WRAIR administrative assistants. It is the responsibility of the Fellows to coordinate any changes to the call schedule, and keep the administrative assistants notified of any changes.
- Physician and non-Physician Fellows will be paired together each month while on call and will be expected to attend morning report together during their rotation. Morning report is typically on Mondays and Fridays at the NNMC. Fellow should coordinate with Dr. Lou Cantilena to ascertain the morning report schedule and location.
- For any consultations the Fellow pairing sees with Clinical Pharmacology Staff or discuss in the Morning Report setting, they will present it at the monthly Division of Clinical Pharmacology/Medical Toxicology Educational Consultation Conference with an in depth analysis and discussion.
- A minimum of four formal consults are required for write up and conference presentation per four week rotation, or in the case of physician Fellows, a minimum of at least ten consults per year of fellowship.
- For information on the Consult Service and the Educational Consultation Conference, please refer to the appendix entitled Consult Service

All Program courses, journal clubs, lectures, and conferences are expected to be attended regularly. These generally are held on Thursdays.

Required Courses in either the 1st or 2nd Year

Clinical Pharmacology Unit/Clinical Trials Unit Rotation (USUHS or WRAIR):

- **Registration Information:**
 - Fellow should coordinate with Dr. Lou Cantilena or COL Colin Ohrt depending on location.
 - One rotation is required; however a second rotation is highly recommended.
 - This course is optional for first or second year participation based on the Fellows other activities
- **Details:** The Rotation evaluation will serve as proof that this was taken.
- **NOTE:** Information regarding the CPU Objectives for the rotation is under the appendix entitled: Required Rotations.

Army Pharmacovigilance Center Rotation:

- **Registration Information:**
 - Fellow should coordinate with COL Trinko Coster (703-681-3161) to set up the rotation.
 - This course is optional for first or second year participation based on the Fellows other activities
- **Details:** The Rotation evaluation will serve as proof that this was taken.
- **NOTE:** Information regarding the Army Pharmacovigilance Center Rotation Objectives is under the appendix entitled: Required Rotations.

National Capital Area Poison Control Center Rotation:

- **Registration Information:**
 - Fellow should coordinate with Dr. Lou Cantilena to set up the rotation.
 - This course is optional for first or second year participation based on the Fellows other activities
- **Details:** The Rotation evaluation will serve as proof that this was taken.
- **NOTE:** Information regarding the National Capital Area Poison Control Center Rotation Objectives is under the appendix entitled: Required Rotations.

Electives

(optional if there is inclination and/or money with permission from Directors)

Center for Drug Evaluation and Research (CDER) Training Course:

- Highly Recommended!
- Valuable training/informational tool for Fellows. Various course topics are offered sporadically. Contact the FDA Office of Training and Communication CDER. The website is: <http://www.fda.gov/cder/> . The current contact (*subject to change*) is Sonya Armstrong (301-847-8716) (sonya.armstrong@fda.hhs.gov).
- Previous CDER topics covered: Drug Development Science-Obstacles & Opportunities, Applying Exposure-Response Concepts in Drug Development and Regulatory Review, Pharmacogenetics, and more.

U.S. Food and Drug Administration (FDA) Advisory Committee Meetings and Conferences:

- Highly Recommended!
- Valuable training/informational tool for Fellows. To initially review meetings/conferences, go to: <http://www.fda.gov/opacom/hpmeetings.html>
- To receive updates on the FDA Meetings, you can sign up for it on the same page.
- Must attend one in a two year cycle

John Hopkins Malaria Research Conference:

- Typically, this is a 2-day conference that occurs in the beginning to mid-March. It is free. Or, a minimal fee can be paid for attendance to lunch.

Tufts Center for the Study of Drug Development:

- **Course Title:** Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation
- **Registration Information:**
 - Register via Fax
- **Website:** <http://csdd.tufts.edu/NewsEvents>
- **REGISTRATION DEADLINES:**
 - Register by mid-October.
- **Cost:** \$3,300 plus travel/lodging/food
- **Course Months:** In February.
- **Course Days:** 5-Day course.
- **Course Location:** Boston, MA

Medical Research Information Technology Systems Trainings:

- Offered through the MeRITS program for free typically at either WRAIR (Bldg 500) or at Ft. Detrick. The following is the website: <http://www.merits.army.mil/training/training.html>
- The following is a sample of the courses taught: Course 100 Series: MeRITS Regulatory Information Systems Training Program; Course 200 Series: Clinical Data Management Training; Course 300 Series: Knowledge Management Essentials for FRED Training; Course 301 Series: Basics for FRED End Users Training; and Case Report Form (CRF) and Serious Adverse Event (SAE) Training.
- For questions about the courses or registration, email: USAMRMC.MeRITS@amedd.army.mil



Clinical Pharmacology Fellow Activity Log

The following is a template that should be used to record the fellow's activities leading to successful program completion. The log should be completed and turned in every 6 months (to include the end of program evaluation mtg.).

Filling out the form (online):

Type over the italicized explanatory descriptions in the form below with your activity information; the boxes will expand to accommodate your input.

Fellow: _____

Period Covering: _____

Evaluation Date: _____

CATAGORY	DESCRIPTION	DATES	STATUS
PLEASE NOTE: When addressing Courses , please include all required classes, plus any electives that you have taken. Please address the area of content addressed by checking the appropriate box, or filling in the other category. Copy and paste as necessary the check list.			
1) Courses:	Course Title: Course Content (please check that which applies): ____ Adverse Drug Reactions ____ Drug Analytical Methods ____ Drug Effects & Dispositions in Special Subjects ____ Drug Regulation & Development ____ Pharmacogenetics ____ Pharmacokinetics ____ Post-Marketing Drug Surveillance ____ Substance Abuse ____ Toxicology/Poisoning ____ Other: _____	Start Date: End Date:	<i>Planned, Attending, Completed, Passed Exam</i>
2) Rotations:	Please check that which applies: ____ Clinical Pharmacology Unit ____ FDA ____ Other: _____ Mentor:	Start Date: End Date:	
	Please check that which applies: <input type="checkbox"/> Clinical Pharmacology Unit <input type="checkbox"/> FDA <input type="checkbox"/> Other: Mentor:	Start Date: End Date:	



Fellow: _____

Period Covering: _____

Evaluation Date: _____

CATAGORY	DESCRIPTION	DATES	STATUS
3) Clinical: Please copy and paste information as needed in new rows.	Morning Rounds: WRAMC	Dates: • •	Topics Covered: • • Patient Population Discussed: • •
	Morning Rounds: NNMCMC	Dates: • •	Topics Covered: • • Patient Population Discussed: • •
	Consults Types: ____ Clinical Pharmacology Fellowship Consult ____ MedWatch ____ Clinical Telecon through OTSG ____ Other: _____	Date:	Patient Information (please check that which applies): ____ Female ____ <i>Pregnant</i> ____ Male Age Group: ____ <i>Pediatric</i> ____ <i>Elderly</i> Cause: • • Results: • •
4) Research Project:	Project Title (once official):		Established On:
	Project Mentor (once official):		Established On:
5) Research Project Progress Report: Please cover the following topics	Proposal Written Information:	Dates: • •	<i>proposal written, presentation given, project underway, completed, final presentation, abstract submitted, publication submitted</i>



Fellow: _____

Period Covering: _____

Evaluation Date: _____

CATAGORY	DESCRIPTION	DATES	STATUS
	Presentation Given Information:	Dates: • •	
	Project Progress Information:	Dates: • •	
	Completed Project Information:	Dates: • •	
	Final Presentation Information:	Dates: • •	
	Abstract Submission Information (please check that which applies): ____ ASCPT ____ ASTMH Other:	Dates: • •	
	Publication Submission Information:	Dates: • •	Journal Submitted to: Article: ____ Accepted ____ Denied
6) Weekly Lectures: Please copy and paste information as needed in new rows.	Title: Presenter: Topic Overview:	Date:	
	Title: Presenter: Topic Overview:	Date:	



Fellow: _____

Period Covering: _____

Evaluation Date: _____

CATAGORY	DESCRIPTION	DATES	STATUS
PLEASE NOTE: When addressing Trainings , please include all trainings, even the mandatory Military Training as the Military Trainings do cover some of the ABCP Requirements of things a Fellow needs to learn such as Ethics.			
7) Trainings: Please copy and paste information as needed in new rows.	Title: Method of Training: _____ Presenter Name: _____ _____ Computer _____ Other: _____ Topic Overview:	Date:	
	Title: Method of Training: _____ Presenter Name: _____ _____ Computer _____ Other: _____ Topic Overview:	Date:	
8) Teaching Activities:	Title: Location: Audience (ex. Med Students or ASCPT Members):	Date:	Your Evaluation Of Your Presentation: External Feedback:
	Title: Location: Audience (ex. Med Students or ASCPT Members):	Date:	Your Evaluation Of Your Presentation: External Feedback:
	Title: Location: Audience (ex. Med Students or ASCPT Members):	Date:	Your Evaluation Of Your Presentation: External Feedback:



Fellow: _____

Period Covering: _____

Evaluation Date: _____

CATAGORY	DESCRIPTION	DATES	STATUS
PLEASE NOTE: When addressing Meeting Attendance , please include all drug development meetings, FDA Advisory Committee Meetings. Copy and paste as necessary the check list.			
9) Meeting/Conferences Attended:	Name of Conference/Meeting: Location: Member:	Dates:	
10) Committee Attendance:	Committee Attended: _____ P & T _____ HURC/IRB _____ Other:	Dates: • •	
	Committee Attended: _____ P & T _____ HURC/IRB _____ Other:	Dates: • •	
11) Other Activities			

Division of Experimental Therapeutics/Clinical Pharmacology Fellowship

Attendance for Seminars 2008-2009

Date	Speaker	Title	Total
Sept. 18	Dr. Philip Colangelo from the FDA	<i>Clinical Pharmacology Studies in Drug Development: Design & Considerations</i>	29 people
Sept. 25 1030-1130	Mr. Jack Balsinger	<i>Qual-Fusion</i>	26 people
Oct. 2	Dr. Sarah Robertson from the FDA	<i>PK/PD and Dose Selection of Anti-Infectives</i>	25 people
Oct. 9	Dr. Joe Bertino	<i>The Use of Antimicrobial Pharmacodynamics to Improve Patient Outcome and Reduce the Development of Resistance: Ready for Prime Time?</i>	22 people
Oct. 16	Dr. Susan Suarez from the FDA	<i>Pharmacokinetics and Regulatory Aspect of Inhaled Drugs</i>	24 people
Oct. 23	COL Colin Ohrt	<i>Leadership Concepts</i>	17 people
Oct. 30	COL Alan Magill	RESCHEDULED	
Nov. 6	Dr. Christian Wolf from Georgetown	<i>Overcoming Drug Resistance to Quinoline Antimalarials by Systematic Side Chain Variations and Pharmacodynamic Analysis</i>	29 people
Nov. 13	Dr. David Sacks from NIAID	<i>In vivo Imaging of Leishmania: Host Cell Interactions following Transmission by Sand Fly Bite</i>	61 people
Nov. 20	Dr. Tim Cote from FDA	<i>An Orphanage of Orphan Drugs for Neglected Tropical Diseases</i>	33 people
Nov. 27		Thanksgiving	Home
Dec. 4	MAJ Jurandir DalleLucca	<i>Fellow's First Research Project Presentation</i>	32 people
Dec. 11		ASTMH Conference	New Orleans, LA
Dec. 18	MAJ Hans Wei	<i>Fellow's First Research Project Presentation</i>	24 people
Dec. 25		HOLIDAY	
Jan. 1		HOLIDAY	
Jan. 8	LTC Bryan Smith	<i>Fellow's First Research Project Presentation</i>	24 people
Jan. 15	Dr. Carl Alving from WRAIR	<i>How Science Works</i>	26 people
Jan. 22	COL Scott Miller	Rescheduled	
Jan. 29	COL Peter Weina	<i>The History of the Artemisinins and Development of Intravenous Artesunate</i>	35 people
Feb. 5	COL Scott Miller	Rescheduled	
Feb. 12 1200-1300	Dr. Kenneth Hastings from Sanofi Aventis	<i>Transition from Pre-Clinical to Clinical: Role of Toxicology in Development of Anti-malarials</i>	29 people
Feb. 19	Dr. Howard Lee from UCSF	<i>Biomarkers in Drug Development</i>	31 people
Feb. 26	Dr. Movchan, Dr. Lemkey, Dr. Rainina, & Dr. Trudil from USIC	<i>United States Industry Coalition, Conus and Oconus Capabilities in Novel Disciplines of Drug Discovery and Drug Delivery Development</i>	22 people
Mar. 5 1200-1300	Dr. Joseph Tonning from FDA	<i>Drug Safety Data Mining</i>	30 people
Mar. 12 1200-1300	Dr. Ruili Huang from the NIH	<i>Compound Cytotoxicity Profiling and Characterization of Toxicity Mechanisms Using Quantitative High-Throughput Screening</i>	24 people
Mar. 19		ASCPT Meeting	Washington DC
Mar. 26	Dr. Shashi Amur from the FDA	Rescheduled	
Apr. 2	Dr. R. Daniel Benz from CDER	<i>The Use of QSAR Computational Toxicology to Predict Toxicity, Adverse Human Effects, and Mechanism/Mode of Action of Pharmaceuticals</i>	
Apr. 9	Dr. Shashi Amur from the FDA	<i>Adverse Drug Reactions and HLA Association</i>	
Apr. 16 1200-1300	Dr. Ike Lee from the FDA	<i>Drug-Therapeutic Protein Interactions</i>	
Apr. 23		Family Day at WRAIR	
Apr. 30		DIV ET Retreat	
May 7	Dr. Peter Hoertz from George Washington Univ	TBD	
May 14 1200-1300	COL Aizen Marrogi	<i>Plants as Therapeutic Molecules Source for Military Medicine Application</i>	
May 21 1200-1300	LTC Louis Macareo	<i>Final Research Project Presentation</i>	
May 28	COL Susan Fracisco	<i>Final Research Project Presentation</i>	

Division of Experimental Therapeutics/Clinical Pharmacology Fellowship
Attendance for Seminars 2007-2008

Date	Speaker	Title	Total
Aug. 16	Dr. David Peyton	<i>Molecules Designed to Overcome the Resistance to CQ found in P. falciparum Malaria</i>	22 people
Sept. 6	COL Alan Magill	<i>ET Antimalarial Drug Product Portfolio</i>	38 people
Sept. 13	Dr. John Lazo from UPDDI	<i>High Throughput Screening</i>	20 people
Sept. 21 Friday 1230-1330	CPT Charlotte Lanteri, Mr. John Notsch, and Dr. Montip Gettayacamin	<i>Animal Models of Malaria: Predictive ability of mouse and Rhesus models and management of our animal resources</i>	28 people
Sept. 27 1500-1600	Dr. Nicholas White from Wellcome Trust	<i>Treating Malaria: The Long and Winding Road</i>	
Oct. 4	CPT Kirsten Smith	<i>Introduction to the FDA and the Review Process- Part 1: Studies through the Initial IND Submission</i>	54 people
Oct. 11 1000-1100	Dr. Jerry Jenkins, Dr. Dejan Milatovic, and Dr. Dana Crawford from CFD Research Corporation	<i>A Systems Biology Approach to Enable Safe Administration of Mefloquine</i>	17 people
Oct. 18 1300-1400	Dr. Christopher Austin from the NIH	<i>The NIH Chemical Genomics Center: Developing Leads for Neglected and Rare Diseases</i>	16 people
Oct. 25 1100-1130	Dr. Geoff Dow	<i>Development of Malaria Prophylaxis Drugs in a Post-DH2000 World</i>	40 people
Oct. 25 1130-1230	COL Colin Ohrt	<i>Plasmodium Antigen-Specific Antibodies as a Surrogate Marker of Malaria Exposure</i>	46 people
Nov. 1 1000-1030	COL Colin Ohrt	<i>ASTMH Presentation: Review of Experimental Therapeutics Chemical Information System for all Compounds Active in Prophylaxis Animal Models</i>	16 people
Nov. 1 1030-1100	COL Pete Weina	<i>ASTMH Presentation: Licensed cGMP Intravenous Artesunate Availability in the Developed World: Light Finally at the End of the Tunnel</i>	16 people
Nov. 1 1100-1130	MAJ David Saunders	<i>ASTMH Presentation: Doxycycline hyclate tolerability and compliance as daily oral malaria prophylaxis in field conditions: experience of the 10th Mountain Division (LI), OEF VII</i>	15 people
Nov. 1 1130-1200	Dr. Kashinath Ghosh	<i>ASTMH Presentation: Molecular identification of the gregarines of phlebotomine sand flies</i>	14 people
Nov. 1 1200-1230	COL Scott Miller	<i>ASTMH Presentation: Diagnosis of Vivax malaria with a focus on the use of rapid Diagnostic tests (RDTs)</i>	5 people
Nov. 15	Dr. Tom Callaghan from Indiana University	<i>We Have the Evidence! So what this IT about?</i>	12 people
Nov. 29	LTC Mike Kozar	<i>Novel Liver Stage Anti-Malarials – Imidizolidinediones</i>	37 people
Dec. 6	COL Susan Francisco	<i>Fellow's First Research Project Presentation</i>	9 people
Dec. 13	MAJ Louis Macareo	<i>Fellow's First Research Project Presentation</i>	16 people
Jan. 10	COL Chris Ockenhouse	<i>Global Human Genome Response Induced by Malaria Vaccines and Early Pre-Symptomatic Malaria Infection</i>	27 people
Jan. 17	Dr. Todd Shearer from GSK	<i>Preclinical DMPK Strategies for Identifying and Progressing Lead Compounds - Making the Most of It</i>	25 people
Jan. 24	CPT(P) Kirsten Smith	<i>Nonclinical Testing of Pharmaceuticals: Studies through the IND Submission</i>	40 people
Jan. 31	CPT Bill McCalmont & CPT Jake Johnson	<i>Hit Discovery Using Chemical Diversity</i>	34 people
Feb. 7	Dr. Joseph Polli from GSK	<i>Overview of Drug Transports: Why they matter in ADME</i>	50 people
Feb. 14	Dr. Jayendra Bhonsle	<i>Application of Computational methods to Drug Design and Discovery</i>	16 people
Feb. 21	Dr. Josh Berman from the NIH	<i>Clinical Issues in the Study of Alternative Interventions</i>	22 people
Feb. 28	Dr. Laura Lee Johnson from the NIH	<i>Biostatistical Issues in the Study of Alternative Interventions</i>	14 people
Mar. 6	COL Colin Ohrt	<i>G6PD Presentation</i>	24 people
Mar. 13	Dr. John Powers from	<i>Evaluating Effectiveness of Medical Interventions: Designing and Interpreting Clinical Trials Results</i>	12 people
Mar. 20	Dr. John Powers from SAIC	<i>Evaluating the Potential Harms of Medical Interventions: What is Risks vs Benefits?</i>	30 people

Mar. 27	Dr. Claudia Golenda	<i>The Types of Agreements Used in Technology Transfer with Parties Outside the Government</i>	24 people
Fri, Apr. 11 1100-1200	LTC(P) Trinka Coster from OTSG	<i>Pharmacovigilance in the Military Healthcare System</i>	17 people
Apr. 17	Dr. Mara Aspinall from Genzyme	<i>Personalized Medicine: Opportunities to Change the Current Paradigm</i>	27 people
Fri, Apr. 18 0930-1030	Dr. Neil Reiner from U. of B.C.	<i>Protein Secretion in Leishmania, Mechanisms and Role in Pathogenesis</i>	26 people
May 1	Dr. Tapash Ghosh from the FDA	<i>Overview of Transdermal and Topical Drug Products: Clinical Pharmacology Perspective</i>	21 people
May 8	Dr. Derek Zhang from the FDA	<i>Renal Impairment Study: When to Study Design and Data Analysis Issues</i>	17 people
May 15	Ms. Elizabeth Arwine from USAMRMC	<i>Intellectual Property Tips for Scientists</i>	20 people
May 22	Mr. John Notsch & Mr. Peter Parker	<i>ET Network Resources Tutorial: CIS, TWiki, and Pipeline Pilot</i>	25 people
May 29	COL Scott Miller	<i>Dose Optimization for Parasite Elimination</i>	36 people
Mon. June 2	Dr. Wai C. Wong	<i>In Pursuit of Treatments for Cancer, Obesity and BPH</i>	18 people
June 12	COL Kevin Abbott from OTSG	<i>Epidemiology of Kidney Injury associated with Oral Sodium Phosphate (OSP) Bowel Purgatives</i>	12 people
June 13	MAJ David Saunders	<i>Final Research Project Presentation to the Department of Medicine at USUHS</i>	5 people
June 19	MAJ David Saunders	<i>Leishmaniasis & Doxycycline</i>	29 people

Clinical Pharmacology Fellowship
Attendance for Lectures
2006-2007

Date	Speaker	Title	Total
Sept. 7	MAJ Saunders	<i>Journal Club</i>	6 people
Sept. 14	Dr. Cantilena	<i>Clinical Consultation Service</i>	6 people
Sept. 21	COL Cannard	<i>Medical Student Presentations</i>	6 people
Sept. 28	Dr. Cantilena	<i>Clinical Consultation Service #2</i>	6 people
Oct. 12	Dr. Craig Brater	<i>Diuretic Resistance</i> (external speaker)	10 people
Oct. 26	MAJ Leary	<i>Intersession Course: Case Preparation</i>	6 people
Nov. 2	COL Ohrt	<i>Tafenoquine Update</i>	7 people
Nov. 9	MAJ Leary	<i>Drug Use in Disease States</i>	5 people
Nov. 30	Dr. Cantilena	<i>Clinical Consultation Service #3</i>	6 people
Dec. 7	MAJ Saunders	<i>Handbook Review</i>	6 people
Dec. 14		<i>DS: Research Project</i>	7 people
Feb. 15	LTC Scott Miller	<i>Post-Antibiotic Effect</i>	16 people
Feb. 22	Dr. Yaning Wang from the FDA	<i>Application of Mathematic Disease Model in Oncology for Survival Prediction</i>	9 people
Mar. 1	COL Alan Magill	<i>Sponsor-Investigator Relations</i>	23 people
Mar. 8	MAJ David Saunders	<i>Journal Club</i>	5 people
Mar. 15	MAJ Kent Bennett	<i>Journal Club</i>	6 people
Mar. 29	LTC Scott Miller	<i>Human Subject Protections in International Research</i>	23 people
Apr. 5	Mr. Mark Tewey from the SigmaTau	<i>Validation of Drugs in Development</i>	21 people
Apr. 12	Dr. Drew Lewis	<i>International Clinical Trials from an Industry Perspective</i>	24 people
Apr. 24	Dr. Christy John from the FDA	<i>Imaging in Drug Development</i>	23 people
May 3	Dr. C. Flexner from John Hopkins	<i>PK and PD of Chemokine Receptor Antagonists: From AIDS to Zebrafish</i>	16 people
May 10	MAJ Kent Bennett	<i>Final Research Project Presentation</i>	8 people
May 17	Dr. Hong Zhao from the FDA	<i>Therapeutic Proteins</i>	13 people
May 24	Dr. Wei Qui & Dr. Jim Wei from the FDA	<i>Drug-Drug Interactions: Clinical Impact and In Vitro Prediction</i>	

**Clinical Pharmacology Fellowship
Tentative Calendar of Review for Boards
2006-2007**

Date	Topic	M & M	Atkinson	Other	Speaker
11 Oct.	Introduction to Clinical Pharmacology and Rational Therapeutics	1			COL Cannard
18 Oct.	Introduction to Clinical Pharmacology and Rational Therapeutics	1			COL Cannard
Oct. 12	Pharmacokinetics: Introduction	23	1 & 2		MAJ Bennett
Oct. 19	Pharmacokinetics: Compartmental analysis of drug distribution		3		MAJ Bennett
Oct. 26	Pharmacokinetics: Drug absorption and bioavailability		4		MAJ Bennett
Nov. 2	Drug Metabolism		11		COL Cannard
Nov. 9	Drug Metabolism		11		COL Cannard
Nov. 30	Pharmacodynamics		18		CPT Sancho
Dec. 7	Drug Transporters		16		COL Cannard
Dec. 21	Pharmacogenetics	22	13		COL Cannard
Jan. 4	Rescheduled Pharmacogenetics	22	13		COL Cannard
Jan. 11	Renal function and dysfunction	6	5 & 6		MAJ Leary
Jan. 18	Renal function and dysfunction (rescheduled to 2/15/07)	6	5 & 6		MAJ Leary
Jan. 25	Renal function and dysfunction (rescheduled to 2/22/07)	6	5 & 6		MAJ Leary
Feb. 1	Liver function and dysfunction (rescheduled to 3/8/07)		2		CPT Sancho
Feb. 8	Adverse Drug Reactions (rescheduled to 3/15/07)	24	25		COL Cannard
Feb. 15	Renal function and dysfunction	6	5 & 6		MAJ Leary
Feb. 22	Renal function and dysfunction	6	5 & 6		MAJ Leary
Mar. 1	Renal function and dysfunction	6	5 & 6		MAJ Leary
Mar. 8	Adverse Drug Reactions	24	25		COL Cannard
Mar. 15	Adverse Drug Reactions	24	25		COL Cannard
Mar. 29	Liver function and dysfunction--Changed to MAJ Saunders Project		2		CPT Sancho
Apr. 5	Drug Interactions--Cancelled and Rescheduled to 4/19/07	25	1st ed: 14, 2nd ed: 15		COL Ohrt
Apr. 12	Drug Toxicity--Cancelled and Rescheduled to 4/24/07	18	1st ed: 15, 2nd ed: 16		MAJ Bennett
Apr. 19	Drug Interactions--Cancelled and Rescheduled to 5/3/07	25	1st ed: 14, 2nd ed: 15		COL Ohrt
Apr. 24	Drug Toxicity	18	1st ed: 15, 2nd ed: 16		MAJ Bennett
May. 3	Drug Interactions--Cancelled and Rescheduled to 5/10/07	25	1st ed: 14, 2nd ed: 15		COL Ohrt
May.10	Drug Interactions #1	25	1st ed: 14, 2nd ed: 15		COL Ohrt
May. 17	Drug Interactions #2	25	1st ed: 14, 2nd ed: 15		COL Ohrt
May. 24	Drug Interactions #3	25	1st ed: 14, 2nd ed: 15		COL Ohrt
May. 31	Pediatric Pharmacology	20	1st & 2nd ed: 23		
June. 7	Geriatric Pharmacology	21	1st & 2nd ed: 24		MAJ Saunders
June. 14	Drugs in Pregnancy and Breast-Feeding Women	19	1st & 2nd ed: 22		CPT Sancho
June. 21	Cardiovascular Drugs and Issues	1			MAJ Saunders
June. 28	Respiratory Drugs and Issues	2			
	GI Drugs and Issues	3 & 4			
	Renal Drugs, Dysfunction, and Issues	6			MAJ Leary
	Neurological drugs and Issues	7			COL Cannard
	Psychiatric Disorders and Issues	8			COL Cannard
	Substance Abuse: Dependence and Treatment	17			
	Musculoskeletal and Conn Tissue Drugs and Issues	10			
	Endocrine and Metabolic Disorders, Drugs, and Issues	9			MAJ Saunders
	Anesthetics, Conscious Sedation, and Pain	15			
	Infectious Disorders and Issues	14			
	Oncologic Disorders and Issues	13			CPT Sancho
	Hematologic Disorders and Issues	12			CPT Sancho
	Dermatologic Disorders and Issues	11			
	Drugs in Systemic Disease				MAJ Leary
	Treatment in the Intensive Care Unit	16			
	Nutrition	5			
	Pharmacodynamics				
	Liver function and dysfunction				



MEMORANDUM OF UNDERSTANDING
BETWEEN
THE WALTER REED ARMY INSTITUTE OF RESEARCH
AND
THE FOOD AND DRUG ADMINISTRATION
AND
THE F. EDWARD HÉRBERT SCHOOL OF MEDICINE
OF THE
THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

SUBJECT: MOU with FDA and USUHS continuing a fellowship training program.

1. Purpose. This Memorandum of Understanding (MOU) documents the affiliation among the Institute, the School, and the FDA in the established Clinical Pharmacology Fellowship Training Program. This affiliation permits the coordination of resources to develop a unified program, maximize efficient utilization of government facilities, and strengthen the joint education and research efforts among the parties.
2. Problem. Military and civilian elements within the Federal Government are separately empowered and funded by Congressional Acts. In working together, they must accommodate legal and monetary restrictions, and assure that each party receives mission benefit from any Agreements arranged.
3. Scope. The Clinical Pharmacology Fellowship Training Program (the Program) consists of two years of training. Fellows may be selected and trained at each year level. Fellows shall be Medical Corps officers on active duty in the U.S. Army, the U.S. Navy, the U.S. Air Force, or the U.S. Public Health Service. Additionally, civilian fellows may also be trained when there is an available source of funding. The Program has been in effect under an MOU between the same parties. The parties to this MOU are:
 - a. The Walter Reed Army Institute of Research (the Institute) is an element of the United States Army. The Institute conducts research on a range of military relevant issues, including naturally occurring infectious diseases, combat casualty care, operational health hazards, and medical defense against biological and chemical weapons.
 - b. The Food and Drug Administration (the FDA) is an agency of the Department of Health and Human Services. The FDA promotes and protects the public health by helping safe and

effective products reach the market in a timely way, and by monitoring products for continued safety after they are in use.

c. The F. Edward Hébert School of Medicine (the School) is a major component of the Uniformed Services University of Health Sciences, an element within the Department of Defense. A fully-accredited educational institution, the School offers professional and academic degrees in medicine, health administration, biomedical sciences, and related fields.

4. Understandings.

This MOU involves the combined and coordinated efforts of the parties to the MOU, and is only amenable to separation of responsibilities as noted below:

a. The School and the Institute will coordinate the technical and support personnel involved in the Program. The FDA's contribution to the Program will be to offer a two-month to four-month internship to second year fellows and potentially clinical pharmacology staff who have not had this component as part of their training. Each party will provide qualified civilian or uniformed personnel who are assigned to serve as mentors.

b. The Program's Fellows will be directly responsible to and under the direction of the Co-Directors of the Program at the School and at the Institute.

c. The Co-Directors of the Clinical Pharmacology Fellowship Training Program will be responsible for the direction of all Fellows. Fellows will be evaluated semiannually by the Co-Directors for the first year fellows and progress monitored as needed during the second year.

d. The FDA's Office of Clinical Pharmacology within the Center for the Drug Evaluation and Research will arrange a two-month to four-month internship in the therapeutic area of interest for second-year Fellows. The Office of Clinical Pharmacology will contact the appropriate review division within the FDA. During this rotation, a member of the Office of Clinical Pharmacology or the appropriate office or review division hosting the internship will be assigned as a mentor (team leader or reviewer) to the Fellow during the period of training. The Fellows will attend Office of Clinical Pharmacology and related review division briefings and other scientific activities. Reviews by the Fellow of protocols and study reports and other submissions will be conducted under appropriate supervision to the extent permitted under applicable statutes and regulations. The rotation should be arranged to allow the Fellow to participate in educational activities sponsored by the FDA such as the Topics in Clinical Trials course, the bimonthly scientific seminar, the annual Academics to the Center for Drug Evaluation and Research course and, if possible, the NDA review course.

e. The parties agree that they will abide by all requirements of the American Board of Clinical Pharmacology, including, but not limited to, those involving the supervision of Fellows, Fellows' work hours, and Fellows' work environment.

5. Resources.

a. The Institute will bear all special costs for training of Army Fellows outside of normal day to day operations. This will include travel costs and, as a minimum, provision of funds sufficient for one trip each year for each fellow to attend a scientific meeting approved by the Fellowship Training Program Co-Directors. Payment for the tuition of courses and books necessary for training in the discipline of clinical pharmacology also will be from the Institute's training fund.

b. There is no reimbursement contemplated between the parties in the fulfillment of this Agreement. In the event the transfer of funds is required in the future, the parties may enter into an interagency agreement pursuant to the Economy Act of 1932, as amended, 31 U.S.C. 1535.

6. Fellows' Eligibility Requirements

The minimum academic and professional qualifications to enter the program are an M.D. or D.O. degree from an accredited institution and training and board eligibility in a medical specialty.

7. Liability

For liability purposes, it is recognized that the three parties to this Agreement all are entities of the United States Government whose employees are covered by the provisions of the Federal Tort Claims Act. In the event a potentially compensable event occurs, the institution that first learns of the event will notify as soon as practicable the point of contact of the other two institutions listed in the agreement.

While assigned to the Program and while performing duties pursuant to this agreement, Fellows, Directors, mentors, and support staff remain employees of the United States performing duties within the course and scope of their Federal employment. Consequently, the provisions of the Federal Tort Claims Act (Title 28, U.S.C. § 1346(b), 2671 – 2680), including its defense and immunities, will apply to allegations of negligence or wrongful acts or omissions by Fellows, directors, mentors, and support staff while they are acting within the scope their duties pursuant to this agreement.

The foregoing represents the broad outline of the agreements of the parties to engage in collaborative training efforts. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds and are further subject to applicable statutes and regulations. This MOU does not affect or supersede any existing or future arrangements among the parties and does not affect the ability of the parties to enter into other agreements or arrangements related to this MOU.

11. Approvals:

FOR the F. Edward Hébert
School of Medicine

FOR the WRAIR

LARRY W. LAUGHLIN, M.D., PH.D.
DEAN

KENNETH A. BERTRAM, COL, MC
WRAIR, Commander

DATE

DATE

FOR the FDA



STEVEN GALSON, MD, MPH.
Director
Center for Drug Evaluation and Research



DATE

MEMORANDUM OF UNDERSTANDING
AMONG
THE WALTER REED ARMY INSTITUTE OF RESEARCH
AND
THE FOOD AND DRUG ADMINISTRATION
AND
THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HÉBERT SCHOOL OF MEDICINE


SUBJECT: Amendment to the WRAIR, FDA, and USUHS MOU Concerning the Clinical Pharmacology Fellowship Program

1. Reference. Economy Act, 31 U.S.C. § 1535.
2. Purpose: Amend the basic MOU so that applicants with the Ph.D. and Pharm.D. degrees may be considered for the Clinical Pharmacology Fellowship Program.
3. Amendment: Change paragraph 6 of the MOU to read:

The minimum academic and professional qualifications to enter the program are a Ph.D., M.D., D.O. or Pharm.D. degree from an accredited institution, and, for applicants with the M.D. or D.O. degree, training and board eligibility in a medical specialty.

4. Effective Date: This amendment is effective on the date of the final signature of the parties.

For the Uniformed Services University
of the Health Sciences




Larry W. Laughlin, M.D., Ph.D.
Dean
F. Edward Hébert School of Medicine

AUG 4 2008

Date

For the Walter Reed Army
Institute of Research




Kent E. Kester, COL, MC
Commander, WRAIR

8/20/08

Date

For the Food and Drug Administration



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research



Date

Objectives for the FDA rotation

1. Gain a broad exposure and understanding of the drug development regulatory process.
2. Meet key FDA personnel in review divisions, especially those in divisions likely to review future anti-malarial drug submissions, or submissions of other drugs relevant to the military. The Division that is responsible for this is the Division of Special Pathogens. They do involve other divisions as needed.

The 3-4 month rotation should be in a Primary Review Division. Special Pathogens is where most fellows have rotated, but any review division that is in the area of the fellow's area of expertise is acceptable. The maximum acceptable number of fellows in any given Division at a time will need to be addressed with Division leadership well before the rotation.

Additionally, a sufficient amount of time should be spent in the Clinical Pharmacology and a Phase IV division so that the fellow understands their basic functions.

3. Attend the Topics in Clinical Trials course (Temple Course). If possible, attend other formal classes dealing with the regulatory process as they are available.
4. Attend meetings between the FDA and industry to gain an appreciation of the different types of meetings and the FDA's perspective of the various regulatory issues during the different phases of drug development. These may include Pre-IND, WE, Pre-NDA, and NDA meetings; in addition, Fellows should be attending the internal FDA meetings that occur before and after such meetings.
5. Attend any FDA Advisory Committee meetings that coincide with the rotation. These typically occur off-site at local hotels. A list of up-coming FDA Advisory Committee meetings may be found at the FDA website.
6. Foster a spirit of cooperation between the FDA and the US Army.
7. Contribute to the FDA's mission of protecting the public health by assisting in the drug development review process.
8. Enhance awareness of the Army's mission in medical research and drug development, and training in Clinical Pharmacology.
9. Understand the basics of how to do a clinical pharmacology review of an IND and NDA. In practice, this done from a medical perspective, as part of a Medical Review. In this way, one gets to simultaneously consider Efficacy and Safety. Fellows should be able to understand the basics as reviewing even an sNDA in only 3 months would take up to nearly all of a Fellow's time.
10. Understand the basics of how to evaluate Phase IV safety data
11. Understand the basics of how to evaluate QTc safety data
12. Understand the basics of how to evaluate drug-drug interaction data

13. Become familiar with the FDA intranet and the posting of internal educational conferences and lectures, invited lecture series, FDA courses, and FDA off-site courses.

14. Become familiar with the FDA library and electronic resources available to the FDA employees.

15. Become familiar with Phase IV evaluation.

CO: 4/17/07; KC/DS: 4/08; CO: 8/08

Setting Up A Clinical Pharmacology Fellow FDA Rotation

Steps

1. Before proceeding, it is recommended that you discuss your FDA Rotation with a Director or staff member to help advise you. Each person's experience for setting up their FDA rotation may be different, but here are some general guidelines to help you. The main thing to remember is to be persistent with this. Plus, you must get your security clearance for the FDA done in a timely manner as that can delay or keep you from participating.
2. IMPORTANT: The total time to process all paperwork is approximately two months if done on a normal time course.
3. Determine the FDA/CDER Division or Office (or individual) where you would like your rotation to take place.
4. Go to the FDA website: <http://www.fda.gov/>
 - a. Go to the organizational chart at: <http://www.fda.gov/oc/orgcharts/orgchart.html> and locate the head of the Division or Office where you want to rotate. Most Fellows will want to rotate in a division of CDER (see the organizational chart at <http://www.fda.gov/oc/orgcharts/cder1.pdf>)
 - b. Then, from the FDA Home Page, go to the "FDA A-Z directory" (left column) at <http://directory.psc.gov/employee.htm> and get the number and or email for the Office or division head where you would like to rotate.
5. Call or email them explaining who you are and what you want to do. Consider attaching your CV. They may then direct you to a POC within their office/division.

NOTE: Some divisions are more accommodating than others. The Clinical Pharmacology Division (Director – Larry Lesko) wants a commitment of 3 months.

6. That POC may never have done this before. Let them know that the Management Officer (MO) for the Office that manages that group of divisions (e.g. Office of Drug Evaluation III) is the FDA POC that helps the Fellow get the paper work done. For the Office of Drug Evaluation I, the MO is/was Tammy Russell at 301-796-1045, White Oak campus, Bldg. 22, Rm 4216. You may also need to forward the Division/Office POC or MO a copy of the current Memo of Understanding between the FDA and WRAIR/USUHS regarding Fellowship rotations there (the Educational Specialist has a copy on file in pdf format).
7. The Management Officer will forward you the following forms:
 - a. An FDA Guest Worker Agreement
 - b. An SF 85 Questionnaire for Non-Sensitive Positions, which allows the FDA to do a background check in order to issue a temporary ID (get this done early, it takes time).

8. After the Fellow completes the documents, they must be given to the POC in the sponsoring FDA Division/Office and they have to sign it. Take the signed documents to the MO who will process them. While there, fill out an ID badge request form (register as a Medical Officer). You will need 2 forms of government ID (driver's license, military ID, passport, social security card, etc.) to complete this form.
9. The Fellow will then need to call Patty Delotch (security) at 301-827-5521 to set up an appointment to get fingerprinted. This happens at the Parklawn office (not White Oak). She will need your completed and FDA POC-signed SF 85 to finger-print you. Once the background check is completed and approved, you will get your ID. The ID will allow you to park on the employee parking deck.
10. The MO will also help you get a logon for the FDA computer system (very helpful), an office to use, and a computer to use (your laptop will not be able to access the system).
11. Get a POC (preferably a physician that is a team leader) that can mentor you and establish a relationship with them.
12. It is recommended that Fellows attend as many meetings as possible, especially those with industry or preparing to meet with industry representatives. While this initially sounds tedious, it is not. A wealth of information and insight is gained by going to these meetings. Take a notebook and take notes during the meetings so that you can ask more questions later, check a source of information, or look something up. The division secretary can print up a weekly division calendar listing all the meetings (do this twice a week on Mondays and Thursdays as meetings change).
13. The FDA computer system will also list a calendar of courses and talks. You have to explore the system since these may be listed in various locations depending on whether they are courses, symposia, or guest lectures. Search for the CDER Weekly Calendar, CDER Courses, Scientific Rounds, CDER Seminars, Visiting Professor Series, New Reviewer Workshop, just to name some of the high yield offerings. The FDA also archives many of the presentation in PowerPoint form.
14. Go to at least one Advisory Committee meeting your division is having during your rotation.
15. The White Oak campus is only a mile or so north of the New Hampshire exit of the beltway.

Clinical Pharmacology Unit (CPU) Rotation Information

Goals for Rotations:

- Develop familiarity with all aspects of regulated clinical trials
- Develop sufficient experience with clinical trials that fellow would qualify/be comfortable executing FDA IND clinical trials as PI upon completion of the fellowship
- Develop sufficient experience with clinical trials that fellow can design and write protocols for FDA IND trials at completion of the fellowship.

Prerequisites before Rotation:

- University of Miami/CITI on-line ethics training
- GCP training course

To Set Up Rotation:

- Contact Dr. Louis Cantilena to set up rotation
 - Work Phone Number: 301-295-3240
 - Email: lcantilena@usuhs.mil
 - Office Location: USUHS, Building 53

Major Performance Objectives:

1. Attend initiation and safety meetings of ongoing protocol.
2. Attend at least one IRB meeting of ongoing protocol.
3. Study Documents:
 - a. Protocol
 - b. Informed consent document
 - c. IRB documents and requirements
 - d. CPU SOPs
 - e. Source document/CRF Review.
 - f. Regulatory Binder Review (key documents: FDA 1572 and list of contents, IRB approvals, SSPs, all communications, all IRB required docs, etc.).
4. Participate/Perform Screening. ((target numbers should remain for each of these))
5. Enrollment/Follow-up of study subjects.
6. Observe test article management.
7. Perform AE assessment.
8. Observe data management review (source entry; CRF entry, database entry, database management).
9. Observe sample management review (PK, routine lab, special lab).
10. Participate in AE reviews.
11. Discuss and review protocol deviations/violations.

12. Observe Quality Control procedures.
13. Observe monitoring visits.
14. Observe IRB Audit if possible.
15. Review statistical analysis plan for ongoing protocols.
16. Review PK analysis plan for ongoing protocols.

Upon Completion of Rotation:

- Forward report and logs documenting completion of the above to the Educational Specialist
- Fill out an evaluation of your mentor/supervisor for your rotation and send to the Educational Specialist
- Have your mentor/supervisor fill out an evaluation of your performance during the rotation and send to the Educational Specialist

Objectives for the Consult Service/ Educational Consultation Conference

Goals for Service/Educational Consultation Conference:

- Physician Fellows: Maintain clinical training and experience
- Physician Fellows: Develop sufficient experience in consultative Clinical Pharmacology and Medical Toxicology
- Non-Physician Fellows: Develop an appreciation of a multidisciplinary team approach to the care of the patient, while developing an understanding of the Clinical Pharmacologist's role within that team
- Non-Physician Fellows: To become familiar with the pathophysiology and treatment of disease states commonly seen, and select safe, efficacious, and cost-effective medications/treatments for their appropriate management
- Non-Physician Fellows: To understand the responsibility and role of the Clinical Pharmacologist in clinical research in the hospital setting

Prerequisites before Rotation:

- CITI on-line ethics training
- Information Services Training
- Physician Fellows: Secure WRAMC/NNMC Privileges
- Non-Physician Fellows: you will need to be supervised by a Credentialed Medical Officer

To do the Consult Rotation:

- 2nd Year Fellows will develop an On-Call Schedule. Once developed, the Fellow will submit it to the fellowship Directors, Fellows, and staff.
 - Each Physician Fellow will be paired with a Non-Physician Fellow. Each rotation should be a month long, with each Fellow rotating the following month.
 - The Fellow pairing will attend Morning Report at NNMC on Mondays and Fridays at 0730
 - Contact Dr. Louis Cantilena to set up rotation
 - Work Phone Number: 301-295-3240
 - Email: lcantilena@usuhs.mil
 - Office Location: USUHS, Building 53
 - For any consultations the Fellow pairing sees with Clinical Pharmacology Staff or discuss in the Morning Report setting, they will present it at the monthly Division of Clinical Pharmacology/Medical Toxicology Educational Consultation Conference with an in depth analysis and discussion.

To do the Educational Consultation Conference:

- The Conference will be once a month during the last week of the month at USUHS, Building 53
 - The Educational Specialist will work with Dr. Cantilena and the Fellows to determine the time and the date of the Conference. A schedule of the Conference will try to be sent to all participants at the beginning of each Semester.
- If there are no consultations for the Fellow pairing, Dr. Cantilena will provide the Fellow pairing with a case in which they present at the monthly Division of Clinical Pharmacology/Medical Toxicology Consultation Conference with an in depth analysis and discussion.

Major Performance Objectives:

By completion of the Consult Rotation/ Educational Consultation Conference and its required presentations, the Fellow will be able to demonstrate competence in the following areas:

- Demonstrate an understanding of the pathophysiology of diseases commonly seen in intensive care unit patients.
- Develop a management strategy for the treatment of these diseases. This list will vary depending on the patients seen by the service or provided for the review.
- Devise a rational pharmacotherapeutic plan for each problem and make appropriate recommendations. In order to achieve this objective the Fellow will:
 - Develop patient profiles for discussion including: medical history, problem lists, medications, and pertinent laboratory data that are relevant to the pharmacokinetic and pharmacodynamic status of the patient.
 - Critically evaluate drug therapy with respect to necessity, rationale, dose, alternative options and influence of disease state and other medications/therapies the patient is receiving.
 - Be able to state therapeutic endpoints and monitoring parameters for efficacy and toxicity.
- Apply pharmacokinetic principles
- Demonstration of skill in providing pertinent drug information and therapeutic suggestions to the staff in a professionally appropriate manner.

Upon Completion of Rotation/Conference:

- Forward report and logs documenting completion/presentation of the above to the Educational Specialist
- Fill out an evaluation of your mentor/supervisor for your rotation and send to the Educational Specialist

Pharmacovigilance Center Rotation Information

Goals for Rotations:

- Develop familiarity with all aspects of pharmacovigilance
- Develop sufficient experience with passive surveillance that fellow would qualify/be comfortable executing WebVDME/Empirica™ tool to perform passive surveillance upon completion of the fellowship
- Develop sufficient experience with pharmacovigilance that fellows can perform rapid analysis of safety signals using Defense Pharmacovigilance Application System upon completion of the fellowship.

Prerequisites before Rotation:

- HIPAA training
- Information Assurance Training
- Statistic course
- Consider obtaining M2 and MDR access
- Include your name on our DUA

To Set Up Rotation:

- Contact COL Trinka Coster to set up rotation
 - Work Phone Number: 301-295-8126
 - Email: trinka.coster@afip.osd.mil
 - Office Location: 1335 East-West Highway, Suite 6-100, Silver Spring, MD 20910

Major Performance Objectives:

****The 6 week rotation should be at the PVC and should include working under the mentorship of COL Trinka Coster**

1. Gain a broad exposure and understanding of the science of pharmacovigilance.
2. Meet and work with personnel at the OTSG Pharmacovigilance Center (PVC).
3. To better understand ADE reporting understanding reporting requirements of the DA Form 4106 and the decision process of being forward to FDA
4. Attend a P&T meeting at NNMC or WRAMC to understand the roles and responsibility of establishing formulary, registries, adverse events, and guidelines and policies
5. Become familiar with passive surveillance tools. Perform an analysis of a drug and drug class and therapeutic class. Become familiar with its use and limitations.
6. Become familiar with the DOD Patient Safety Center and how it monitors medical errors and become familiar with medication error reporting tools.
7. Become familiar with the USAMMDA Pharmacovigilance tool. Understand the basics of how to evaluate safety data
8. Become familiar with the DMSB, how it receives and evaluates device problems and standardizes devices.
9. Become familiar with the Defense Pharmacovigilance Application System. Understand the data elements the use and limitations of using claims data for safety surveillance. Understand how to perform a rapid analysis and its limitations.

Upon Completion of Rotation:

- Forward report and logs documenting completion of the above to the Educational Specialist
- Fill out an evaluation of your mentor/supervisor for your rotation and send to the Educational Specialist
- Have your mentor/supervisor fill out an evaluation of your performance during the rotation and send to the Educational Specialist



Mentor/Faculty Evaluation of Clinical Pharmacology Fellow Performance

Please fill-in the following blanks.

Fellow:	Mentor:
Date(s) of Experience:	Service/Location:
Number Hours / Days with Fellow:	Title of Experience:

Please rate the fellow's performance using the following statements and scale where 1 is equal to low agreement with the statement and 5 is equal to high agreement with the statement (NA=not assessed).

		LOW				HIGH
A. KNOWLEDGE:						
	The fellow understands...					
1.	scientific / research methods.	NA	1	2	3	4 5
2.	drug development.	NA	1	2	3	4 5
3.	clinical diagnosis / treatment of ADEs.	NA	1	2	3	4 5
B. PERSONAL/INTERPERSONAL CHARACTERISTICS:						
	The fellow...					
1.	is able to work independently.	NA	1	2	3	4 5
2.	works well with others.	NA	1	2	3	4 5
3.	seeks advice appropriately.	NA	1	2	3	4 5
4.	accepts feedback appropriately.	NA	1	2	3	4 5
5.	shows confidence / professional maturity.	NA	1	2	3	4 5
6.	shows initiative in approaching assignments.	NA	1	2	3	4 5
C. WORK EFFECTIVENESS:						
	The fellow...					
1.	carries out duties in a timely manner.	NA	1	2	3	4 5
2.	is articulate in presenting information orally.	NA	1	2	3	4 5
3.	is able to write effectively.	NA	1	2	3	4 5



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WHAT ARE THE STRENGTHS OF THIS FELLOW?

***WHAT SPECIFIC RECOMMENDATIONS HAVE YOU MADE TO THIS FELLOW TO
IMPROVE HIS / HER KNOWLEDGE, SKILLS, AND CAPABILITIES?***

Mentor/Faculty Signature: _____

Date: _____



**Walter Reed Army Institute of Research and Uniformed Services University of the
Health Sciences Clinical Pharmacology Fellowship Training Program**

***Fellow's Evaluation of His / Her Experience During a Project or
Rotation***

Project(s) or rotation: _____

Mentor(s): _____

Fellow: _____ Date(s): _____

In the space provided please write your comments relating to each of the areas listed below. Additional comments may be written on the reverse side of this sheet. Thank you.

Teaching (effectiveness, appropriateness for level; before, during, after):

Your involvement (level of responsibility, feeling part of team):

Attitude of staff member(s) (receptive to questions, facilitating role, attention):

Please return completed form to your Program Director's Admin. Assistant



Evaluation of Clinical Pharmacology Fellow Oral Presentation

Please fill-in the following blanks.

Fellow:

Evaluator: (optional)

Date:

Time: (length)

Title of Presentation:

Please rate the fellow's presentation using the following statements and scale where 1 is equal to low agreement with the statement and 5 is equal to high agreement with the statement.

	LOW					HIGH
1. The fellow was a credible presenter on the topic.	1	2	3	4	5	
Comments:						
2. The fellow presented a comprehensive amount of information.	1	2	3	4	5	
Comments:						
3. The presentation was understandable.	1	2	3	4	5	
Comments:						
4. The presentation was focused.	1	2	3	4	5	
Comments:						



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5. *The presentation was complete.*

Comments:

LOW HIGH

1 2 3 4 5

6. *The presentation style was engaging.*

Comments:

1 2 3 4 5

7. *The fellow responded well to questions.*

Comments:

1 2 3 4 5

8. *The presentation challenged me to think.*

Comments:

1 2 3 4 5

9. *The audio/visual material was well-prepared and useful.*

Comments:

1 2 3 4 5

10. *The handout material was well-prepared and useful.*

Comments:

1 2 3 4 5

Please utilize the space below for additional comments:



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Fellow Semi-Annual Evaluation Form

Fellow: _____ **Period of Performance:** _____

**Please check (✓) the appropriate box*

<i>Performance Area</i>	<i>Unsatisfactory</i>	<i>Satisfactory</i>	<i>Outstanding</i>	<i>Not Applicable</i>
Participation				
Didactic / Knowledge				
Research				
Clinical				
Professionalism				
Ethical Behavior				
Interpersonal / Communication				

Summary of Fellow's Accomplishments:

Summary of Individual Director Evaluation of Fellow:

Recommendations made to Fellow by USUHS & WRAIR Directors:

Feedback from Fellow:

Fellow Signature

Date

USUHS Director Signature

Date

WRAIR Director Signature

Date



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Fellow's Annual Program Evaluation

Date: _____

This confidential questionnaire is to be completed by each fellow and provided to the program director's administrative assistant.

1. Rate the following activities on a scale from 1-5 where **1 = poor and 5 = outstanding**. If you have not completed a certain task at this point, please indicate by circling N/A. Provide comments on the next page, especially for those activities that received a score of 1 or 2.

- | | | | | | | |
|---|---|---|---|---|---|-----|
| a. Pharmacology Course (USUHS) | 1 | 2 | 3 | 4 | 5 | N/A |
| b. IPPCR course (NIH) | 1 | 2 | 3 | 4 | 5 | N/A |
| c. PCP Course (NIH) | 1 | 2 | 3 | 4 | 5 | N/A |
| d. Clinical Pharmacology Course (USUHS) | 1 | 2 | 3 | 4 | 5 | N/A |
| e. Statistics 500M (FAES) | 1 | 2 | 3 | 4 | 5 | N/A |
| f. Journal Clubs | 1 | 2 | 3 | 4 | 5 | N/A |
| g. Weekly Seminars | 1 | 2 | 3 | 4 | 5 | N/A |
| h. GCP Course (_____) | 1 | 2 | 3 | 4 | 5 | N/A |
| <i>(please note the course taken)</i> | | | | | | |
| i. Ethics Course | 1 | 2 | 3 | 4 | 5 | N/A |
| j. Clinical Research Unit Rotation | 1 | 2 | 3 | 4 | 5 | N/A |
| k. Clinical Pharmacology Consultation Rotations | 1 | 2 | 3 | 4 | 5 | N/A |
| <i>(WRAMC/NNMC)</i> | | | | | | |
| l. FDA Rotation (_____) | 1 | 2 | 3 | 4 | 5 | N/A |
| <i>(please note the FDA division)</i> | | | | | | |
| m. Research Project(s) | 1 | 2 | 3 | 4 | 5 | N/A |
| n. Oral Presentation (Proposal) | 1 | 2 | 3 | 4 | 5 | N/A |
| o. Oral Presentation (Final) | 1 | 2 | 3 | 4 | 5 | N/A |
| p. ASCPT Meeting | 1 | 2 | 3 | 4 | 5 | N/A |
| q. ASTMH Meeting | 1 | 2 | 3 | 4 | 5 | N/A |



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Comments on Question 1 items (list letter of the activity before the comment):

2. Rate the following fellowship structural components on a scale from 1-5 where **1 = poor and 5 = outstanding**. Provide comments below:

a. Teaching Faculty	1	2	3	4	5	N/A
b. Office Space	1	2	3	4	5	N/A
c. Computers	1	2	3	4	5	N/A
d. Administrative Support (personnel, finance, travel, etc.)	1	2	3	4	5	N/A
e. Overall rating for the fellowship	1	2	3	4	5	N/A

Comments on Question 2 (list letter of the activity before the comment):

3. What fellowship factors do you consider conducive to the acquisition of skills and knowledge and demonstration of clinical pharmacology competencies?



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4. What fellowship activities were planned, but not provided?

5. Please suggest measures that would enhance the program for future fellows.

6. Please convey your thoughts on improving the fellowship program and handbook (optional).

***Note: Please attach another sheet if additional space is necessary*



Clinical Pharmacology Fellowship Graduate

<i>Years</i>	<i>Fellow</i>	<i>Date Started</i>	<i>Date Graduated</i>	<i>CP/AP Board Certified</i>	<i>From</i>
80 - 81	Stambler, Nancy - MS	1-JUL-80	30-JUN-81		was a USUHS MS Student
80 - 81	Perlin, Elliot - MD	1-JUL-80	30-JUN-81	1993	was stationed USN, NNMC
81 - 83	Mell, Leroy - PhD	1-JUL-81	30-JUN-83		was stationed USN, NNRC
81 - 84	Ezra, David - MD	1-JUL-81	30-JUN-84		was from U.Tel Aviv, Israel
82 - 83	Platzer, Rudi - MD	1-JUL-82	30-JUN-83		was from U. Bern, Switzerland
82 - 84	Shmuklarsky, Mosha - MD	1-JUL-82	30-JUN-84		was from UCSF
83 - 83	Perkins, Stanley - MD	1-JAN-83	30-DEC-83		was from WRAIR
83 - 84	Chen, Benjamin - MD	1-JUL-83	30-JUN-84		was from UCSF
84 - 86	Haim, Nitin - MD	1-JUL-84	30-JUN-86		was from U.Tel Aviv, Israel
85 - 87	Hill, Vincent - MD	1-JUL-81	30-JUN-83		was from Howard U.
85 - 88	Fleischer, Nicholas - PhD	1-JUL-85	30-JUN-88		was from USUHS
86 - 87	Lehmann, Craig - PharmD	1-JUL-86	30-JUN-87		was from USAF

Clinical Pharmacology Fellowship Graduates

<i>Years</i>	<i>Fellow</i>	<i>Date Started</i>	<i>Date Graduated</i>	<i>CP/AP Board Certified</i>	<i>Destination</i>	<i>Primary Specialty</i>	<i>Sub-Specialty</i>
81 - 82	Berenberg, Jeffry - MD	1-JUL-81	30-JUN-82			Oncology	
86 - 88	Murphy, Gail - MD	1-JUL-86	30-JUN-88		Industry	Pediatrics	Neonatology
88 - 90	Brueckner, Ralf - MD	1-JUL-88	30-JUN-90		Industry	Pediatrics	
90 - 92	Ferguson, Clifford - MD	1-JUL-90	30-JUN-92		Academics	Internal Medicine	Nephrology
90 - 92	Oleshansky, Marvin - MD	1-JUL-90	30-JUN-92	1994	WRAMC	Psychiatry	
91 - 93	Marino, Mark - MD	1-JUL-91	30-JUN-93		Industry	Internal Medicine	
91 - 94	Geraci, Stephen - MD	1-JUL-91	30-JUN-94		Academics	Internal Medicine	Cardiology
91 - 94	Honig, Peter - MD	1-JUL-91	30-JUN-94	1994	Industry		
92 - 94	Wesche, David - MD	1-JUL-92	30-JUN-94		Industry	Internal Medicine	



Clinical Pharmacology Fellowship Graduates

<i>Years</i>	<i>Fellow</i>	<i>Date Started</i>	<i>Date Graduated</i>	<i>CP/AP Board Certified</i>	<i>Destination</i>	<i>Primary Specialty</i>	<i>Sub-Specialty</i>
92 - 95	Graumlich, James - MD	1 JUL-92	30-JUN-95	2001	Academics	Internal Medicine	
93 - 95	Hough, David - MD	1-JUL-93	30-JUN-95		Clinical Practice (New Hope, PA)	Psychiatry	
93 - 96	Goldman, Steve	1-JUL-93	30-JUN-96		Industry, Consultants	Psychiatry	
94 - 96	Leo-Uhl, Kathleen - MD	1-JUL-94	30-JUN-96		FDA	Family Practice	
95 - 97	Kieffer, Lydia - PharmD	1-JUL-95	30-JUN-97		FDA		
95 - 97	Ohrt, Colin - MD (Co-Director)	1-JUL-95	30-JUN-97	2003	WRAIR	Internal Medicine	
95 - 98	Pavlova, Tatiana-MD, PhD	1-JUL-95	30-JUN-98		Academics	Obstetrics-Gyn, Pediatrics	
96 - 98	Bonner, Mark - MD	1-JUL-96	30-JUN-98		Private Practice	Dermatology	
00 - 02	Remich, Shon - MD	1-SEP-00	31-AUG-02		WRAMC	Pediatrics	Allergy/Immun.
00 - 02	Riel, Michael - MD	1-JUL-00	30-JUN-02		Private Practice (Spartansburg, SC)	Internal Medicine	Gastroenterology
01 - 03	Coster, Trinka - MD	1-JAN-01	31-DEC-03		OTSG	Internal Medicine	
02 - 04	Barker, Tamra - MD	1-JUL-02	30-JUN-04		Private Practice	Preventive Medicine	
02 - 04	Medlock, Matthew - MD	1-JUL-02	30-JUN-04	2005	Industry	Internal Medicine	
03 - 05	Leary, Kevin - MD	1-JUL-03	30-JUN-05	2007	USAMMDA	Internal Medicine	
04 - 06	Cannard, Kevin - MD	1-JUL-04	30-JUN-06	2007	USUHS	Neurology	Move. Disorders
05 - 07	Bennett, Kent - DO	1-JUL-05	30-JUN-07		WRAIR, ET	Preventive Medicine	
06 - 08	Saunders, David - MD	1-JUL-06	30-JUN-08		AFRIMS	Internal Medicine	
07 - 09	Fracisco, Susan - MD	1-JUL-07	30-JUN-09		WRAIR, Current MD Fellow	Psychiatry	Child Psychiatry
07 - 09	Macareo, Louis - MD	1-JUL-07	30-JUN-09		WRAIR, Current MD Fellow	Internal Medicine	
08 - 10	Smith, Bryan - MD	1-JUL-08	30-JUN-10		WRAIR, Current MD Fellow	Family Practice	
08 - 10	DalleLucca, Jurandir - PhD	1-JUL-08	30-JUN-10		WRAIR, Current PhD Fellow		
08 - 10	Wei, Hans - PhD	1-JUL-08	30-JUN-10		WRAIR, Current PhD Fellow		
09 - 11	DiTusa, Charles - PhD	1-JUL-09	30-JUN-11		WRAIR, PhD Fellow starting in July '09		
09 - 11	Lanteri, Charlotte - PhD	1-JUL-09	30-JUN-11		WRAIR, PhD Fellow starting in July '09		

****Co-Director:** Dr. Louis Cantilena became a Diplomat in 1991.

Fellows' Orientation 2008

Date of Orientation	Time of Orientation	Room Location	Presenter	Topic
Wednesday, 9 July	1100-1200	1W77	COL Alan Magill	Division Director/Science Director: Division Structure, Portfolio, Target Product Portfolio, Teams
Wednesday, 9 July	1400-1500	1W78	Dr. Claudia Golenda	ORTA Training
Thursday, 10 July	0930-1200	1W77	LTC Mike Kozar	A4 Leader: AIBS Presentation/Funded Portfolio; A4 Exit Criteria Drug Concentration Analysis/Trouble Shooting; Mass Spec
Friday, 11 July	0930-1100	Main Con Rm, CTC in 2West	COL Janine Babcock	Clinical Trials Unit Leadership
Friday, 11 July	1400-1600	1W81	LTC(P) Trinka Coster	OTSG & Referrals
Friday, 11 July	1900	COL Ohrt's House		COL Ohrt's Welcome Get-Together
Tuesday, 15 July	0915-1300	USUHS, Building 53	Dr. Louis Cantilena	USUHS Overview; CPU Information; In-Process at USUHS
Wednesday, 16 July	0830-1030	Tcon (call in directions below)		SRT review of Tafenoquine treatment study Integrated Safety Output
Wednesday, 16 July	1030-1230	2N61	Dr. Tom Hudson	Q Leader: AIBS Presentation/Funded Portfolio
Wednesday, 16 July	1330-1530	3A05	CPT Jake Johnson	Malaria Drug Sensitivity Testing; Lab Introduction
Thursday, 17 July	1000 <i>until potentially the end of the day</i>	1W80 (room reserved from 0900-1600)	Dr. Susan Charman	
Friday, 18 July	1000-1200	1W77 (room reserved from 0900-1600)	Dr. Susan Charman	
Monday, 21 July	1000-1100	Auditorium	CAPT Mark Beavers	FY10 Kick Off of the MIDRP process
Monday, 21 July	1300-1500	2A03/05	COL Peter Weina	AQ Leader: Current status of AS Development/Funded Portfolio; Leish Diagnostics; FRED
Tuesday, 22 July	0930-1230	2A03/05	COL Colin Ohrt	RQ Leader: AIBS Presentation/Funded Portfolio; Antimalarial Drug Development; Malaria Microscopy: CoE, Failed Clinical Trials
Tuesday, 22 July	1400-1600	2A03/05	CPT Charlotte Lanteri	Animal Efficacy Models
Wednesday, 23 July	0900-1200**	2N68	Mr. Juan Mendez	<i>Leish Lab Orientation: LTC Bryan Smith</i>
Thursday, 24 July	0900-1100	3A05	MAJ Victor Melendez	Metabolic stability, Drug-drug interactions, CaCO2
Friday, 25 July	1000-1500ish	2N62	Dr. Qigui Li	PK Information: Rat Model/Non-Mem
Tuesday, 5 August	1400-1500	Benhke Auditorium		Commander's Call: Attendance Mandatory
Wednesday, 6 August	1000-1200	GW52	Mr. John Notsch	Chemical Information
Wednesday, 6 August	1400-1500	1W58	Ms. Patricia Lacey	MATS
Thursday, 7 August	1000-1130	FDA White Oak Campus (address below)	Dr. Shiew Mei Huang	FDA Orientation
Friday, 8 August	1000-1300	1W78	COL Colin Ohrt	SPSS Basics, CrossGraphs Basics, Endnote in a Nutshell
Wednesday, 13 August	1200	Call In Information Below	Ms. Julie Nelson	FDA Guidance Club
Monday, 18 August	0900-1200**	2N68	Mr. Juan Mendez	<i>Leish Lab Orientation: MAJ Hans Wei</i>
Monday, 18 August	1230-1530**	2N68	Mr. Juan Mendez	<i>Leish Lab Orientation: MAJ JJ DalleLucca</i>
Tuesday, 19 August	0800-1700	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	FDA PK/PD Course: MAJ Hans Wei, LTC Louis Macareo, Dr. Qigui Li
Wednesday, 20 August	0800-1700	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	FDA PK/PD Course: MAJ Hans Wei, LTC Louis Macareo, Dr. Qigui Li
Thursday, 21 August	0800-1700	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	FDA PK/PD Course: MAJ Hans Wei, LTC Louis Macareo, Dr. Qigui Li
Monday, 25 August	1330-1530	1A06	MAJ Kirsten Smith	Analytical Methods: Course #1
Tuesday, 26 August	1000-1100	1A06	Dr. Hla Myint	Introduction to Her Project
Tuesday, 26 August	1330-1530	1A06	MAJ Kirsten Smith	Analytical Methods: Course #2
Wednesday, 27 August	1200-1300	1A06 for 27 Aug/2A06 for 3 Sept-on: Call In Information Below	Ms. Julie Nelson	FDA Guidance Club - MARK YOUR CALENDARS, this will be occurring every other week
Tuesday, 2 September	1000-1300	1A06	COL Colin Ohrt	Orientation
Wednesday, 10 September	1300-1400	2A06	COL Colin Ohrt	Back-Up Department Meeting Date
Thursday, 11 September	0930-1100	1A05	LTC Bryan Smith	Journal Club based off of Drs. Charman's Articles
Monday, 8 September	TBD	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	Introduction to PK
Tuesday, 9 September	TBD	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	Introduction to PK
Wednesday, 10 September	TBD	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	Introduction to PK
Thursday, 11 September	TBD	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	Introduction to PK
Friday, 12 September	TBD	FDA White Oak Campus (address below, minus room location)	Dr. Jeffrey Tworzyanski	Introduction to PK
Monday, 15 September	0800-1730	Marriott Bethesda Pooks Hill, Bethesda	FDA/DIA	FDA Critical Path Initiative
Tuesday, 16 September	0830-1500	Marriott Bethesda Pooks Hill, Bethesda	FDA/DIA	FDA Critical Path Initiative
Tuesday, 16 September	1400	FDA, Building 10	Dr. Juan Lertora	Director, Clinical Pharmacology Program; NIH Clinical Center
Thursday, 18 September	1100-1230	1W81	Dr. Philip Colangelo	Analytical Methods: Course #3
Monday, 22 September	1100-1230	1W78	Dr. Ference & COL Miller	IRB Basics for Investigators and Research Staff
Wednesday, 1 October	1700-1830	2A03/05	Monash University Tcon	
Thursday, 25 September	1030-1130	1W81	Mr. Jack Balsinger	Lecture Series - MARK YOUR CALENDARS, this will be occurring every week
Thursday, 2 October	1100-1230	1W77	Dr. Sarah Robertson	Lecture Series - MARK YOUR CALENDARS, this will be occurring every week
Thursday, 2 October	1330-1500	1A06	COL Ohrt	Review, Journal Club, Department Meetings - MARK YOUR CALENDARS, this will be occurring every week
**Please Note: The session in italics are for individuals. The names for that session are in bold under Topic.				
WEEKS Free:	28 July - 1 August 11 - 15 August			
CALL IN INFORMATION:	Primary Dial-In: 1 (877) 218-2237 Passcode: 9724576#	ADDRESS:	CDER Office building 51, Rm 3188 White Oak 10903 New Hampshire Avenue Silver Spring, MD 20993	
		When arrive, you can call:	Marchette Alexander, 301-796-2450 Dr. Shiew-Mei Huang, 301-796-1541	



Orientation Evaluation Feedback from 2008 New Fellows

1-5 where **1 = poor** and **5 = outstanding**

- a. Session by COL Alan Magill: Division of Experimental Therapeutics Overview 3: 1 person; 5: 2 people
• Topics Discussed: division structure, portfolio, target product portfolio, teams
Comments:
- b. Session by Dr. Claudia Golenda: ORTA Training 3: 1 person; 4: 1 person; 5: 1 person
Comments:
- c. Session by LTC Mike Kozar 3: 1 person; 5: 2 people
• Topics Discussed: A4 Leader: AIBS Presentation,/Funded portfolio; A4 Exit Criteria Drug Concentration Analysis/Trouble Shooting; Mass Spec
Comments:
- d. Session by COL Janine Babcock: Clinical Trials Unit Overview 4: 2 people; 5: 1 person
Comments:
• Nice overview of regulated activities.
- e. Session by LTC(P) Trinko Coster: OTSG & Referrals 2: 1 person; 4: 2 people
Comments:
- f. Welcome Party by COL Colin Ohrt 4: 1 person; 5: 2 people
Topics Discussed: USUHS Overview; CPU Information; In-Process at USUHS
Comments:
• Helpful, but perhaps a few fewer persons and some more formal introductions would be helpful
- g. Welcome Party by COL Colin Ohrt 3: 1 person; 5: 2 people
Topics Discussed: USUHS Overview; CPU Information; In-Process at USUHS
Comments:
- h. Session by Dr. Louis Cantilena: 4: 2 people; 5: 1 person
Comments:
- i. Session by Dr. Tom Hudson N/A: 1 person; 3: 1 person; 4: 1 person
• Topics Discussed: Q Leader: AIBS Presentation/Funded Portfolio
Comments:
- j. Session by CPT Jake Johnson 3: 1 person; 4: 1 person; 5: 1 person
• Topics Discussed: Malaria Drug Sensitivity Testing; Lab Introduction
Comments:
- k. Session by COL Peter Weina 3: 1 person; 5: 2 people
• Topics Discussed: AQ Leader: Current status of AS Development/Funded Portfolio; Leish Diagnostics; FRED
Comments:
- l. Session by CPT Charlotte Lanteri: Animal Efficacy Models 3: 1 person; 5: 2 people

Comments:

- m. Session by Mr. Juan Mendez: Leish Lab Orientation 4: 2 people; 5: 1 person
Comments:
- n. Session by MAJ Victor Melendez 4: 1 person; 5: 2 people
• Topics Discussed: Metabolic stability; Drug-Drug Interactions, CaCO₂
Comments:
- o. Session by Dr. Qigui Li 3: 2 people; 4: 1 person
• Topics Discussed: PK Information: Rat Model/Non-Mem
Comments:
• We would benefit to have this meeting after PK/PD course at the FDA
- p. Session by Mr. John Notsch: Chemical Information 3: 2 people; 4: 1 person
Comments:
- q. Session by Ms. Patricia Lacey: MATS N/A: 1 person; 2: 1 person; 4: 1 person
Comments:
• Doesn't need a separate appointment. Incorporate information into another orientation lecture. You can meet her when you actually have a need later.
- r. Session by Dr. Shiew Mei Huang from the FDA N/A: 1 person; 4: 1 person; 5: 1 person
Comments:
• Enthusiastic instructor and an excellent POC for us at the FDA.
- s. Session by Dr. Hla Myint 3: 1 person; 4: 1 person; 5: 1 person
Comments:
- t. Session by Dr. Juan Lertora from the NIH N/A: 1 person; 4: 1 person; 5: 1 person
Comments:
- u. Session by COL Scott Miller & Dr. Jody Ference: N/A: 1 person; 4: 2 people
• Topics Discussed: IRB Basics for Investigators & Research Staff
Comments:
• Not necessary for Fellows with research experience, but a good overview for others.
- v. Sessions by COL Colin Ohrt 3: 1 person; 5: 2 people
Comments:
- w. General Comments on Orientation:
- I found the orientation too extensive and complex. In my opinion, most of the meetings with had could have waited for a personal meeting as we engage in projects/people. Also, most of our meetings where potential matches for projects, I felt the presentations were incomplete without input from opportunities at USUHS or WRAMC. Overall, I enjoyed and learned big deal of the structure of Division of ET.
 - Analytic Methods sessions with MAJ K. Smith were the best presented and helpful session of the entire orientation. She is to be commended!
 - The orientation is well designed and conducted.
 - This program is the best training program I have experienced in my career.



Orientation Evaluation Feedback from 2007 New Fellows

1-5 where **1 = poor** and **5 = outstanding**.

- a. Session by COL Magill: Division of Experimental Therapeutics Overview 5: 2 people
- Topics Discussed: division structure, portfolio, target product portfolio, teams
- Comments:
- Very good introduction to the mission of the department, but especially the vision and “Commander’s Intent”
- b. Session 1 by LTC Kozar: Overview/Introduction for Task A4 4: 1 person; 5: 1 person
- Topics Discussed: funded proposals, how it relates to the portfolio, etc.
- Comments:
- Open discussion and very useful. Learned a great deal during the talk and it is obvious that LTC Kozar can be approached in the future for any other questions.
- c. Session 2 by LTC Kozar: Exit Criteria for Task A4 4: 2 people
- Comments:
- Document presented is a work in progress, but the discussion was very useful.
- d. Session by CPT Lanteri: Animal Efficacy Models Overview 4: 1 person; 5: 1 person
- Topics Discussed: methods and interpretation of the in vitro and animal models
- Comments:
- Excellent powerpoint
 - Thorough, knowledgeable and was able to place the animal models within the context of what the department does in general.
- e. Session by MAJ Melendez: Metabolism Overview 5: 2 people
- Topics Discussed: assays the lab routinely does focusing on what standard human use drugs look like in the models
- Comments:
- Provided excellent resources
 - What he did not readily know or waste our time with, he provided us with other ways to access the information and links.
- f. Session by COL Babcock: Clinical Trials Unit Overview 3: 1 person; 4: 1 person
- Topics Discussed: clinical trials unit at the WRAIR
- Comments:
- Adequate
 - Clearly enthusiastic about what we do here, which is an infectious attitude. I did get the feeling that she was not quite as approachable as the others, but that is only on a scare where most everyone here is exceedingly approachable.
- g. Session by Dr. Hudson: AIBS Presentation/Funded Portfolio 5: 2 people
- Comments:
- gave an excellent overview of MIDRP
 - Yet another person who did a great job placing what they do in context and engaged in good open discussion.



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- h. Session by CPT Johnson: Lab Overview 4: 1 person; 5: 1 person
- Topics Discussed: malaria drug sensitivity and lab safety
- Comments:
- Nice overview
 - I regret that I had to leave this lecture a little early, and I really did not want to. Who can say that about a lecture on lab processes? This was an important lecture and really got to the heart of how the lab does business.
- i. Session 1 by COL Weina/Mr. Melendez: Leish Diagnostics Overview 5: 2 people
- Topics Discussed: leish diagnostics in the lab
- Comments:
- Excellent!!
 - I have never met someone so excited about what they do. We went through the process of leish. Identification hands-on and had a great discussion about the past and future. Very informative.
- j. Session 2 by COL Weina: FRED Overview 5: 1 person; 1 person did not respond w/ rating
- Session 2 by COL Weina: AS Overview 5: 1 person; 1 person did not respond w/ rating
- Topics Discussed: current status of AS development and funded portfolio
- Comments:
- Excellent!!
 - Provided personal and truthful insights into a portion of what we do that is more or less a few steps beyond what we normally do. Clearly and expert and very busy, but took the time to explain the basics and history of a project that is highly progressed.
- k. Session by Dr. Li: WinNonLin 3.5: 1 person; 5: 1 person
- Session by Dr. Li: Rat Model 3.5: 1 person; 5: 1 person
- Comments:
- WinNonLin review should be scheduled for October/November
 - Perhaps this should be scheduled until after we have a few Clin Pharm lectures (NIH Course). I had difficulty understanding subject because I did not understand the basic concepts.
 - Sometimes a little difficult to understand, but his discussion was quite good and his exercises were useful. Somehow, he made something I have never understood make complete sense. It was great working with his assistants in the lab. They are all very happy to explain how/why they do what they do. It was really enjoyable.
- l. Session by COL Ohrt: AIBS Presentation/Funded Portfolio 4: 1 person; 5: 1 person
- Session by COL Ohrt: CoE, failed clinical trials 5: 1 person; N/A: 1 person
- Comments:
- Presentation of the portfolio and all the lectures that COL Ohrt has given us have provided us the opportunity to ask the “really stupid questions” and place ourselves quite well within the universe of what ET does and how things happen. He clearly wants us to understand and is always thinking about what is the best path forward for our fellowship and career, even during a presentation of the portfolio. I do not recall having a lecture specifically on failed clinical trials.



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m. Session by Mr. Notsch: CIS Overview

4: 1 person; 1 person did not respond w/ rating

Comments:

- Probably should be scheduled earlier and be at least 3 sessions. There was so much information to digest.
- This man is a genius. I actually felt sorry for him that he had to dumb-down computer stuff for two novices, but he did not complain and we actively went through some searches during his hands-on presentation. He presents a work product that I think would normally take 3 times the people and money to produce.

n. Session by Dr. Cantilena: Clin Pharm Unit USUHS

4: 1 person ; 5: 1 person

- Topics Discussed: overview of the Clinical Pharmacology Unit at USUHS and CPU rotation

Comments:

- Met 1-on-1; also training was excellent yesterday.
- Very welcoming and informative. Open discussion about the role Clin Pharm and a unique perspective of life on the civilian side of the equation. I hope we can work with him more closely and glean more from him.

o. General Comments on Orientation:

- Actually, this was the best orientation I have ever had.
- I promise that I do not generally have such a “halo effect” when rating presentations, but the simple fact is everyone has been knowledgeable, enthusiastic and approachable. It think it would be very useful to place a full day of the talk similar to Donna Dorozinsky on the fundamentals of the Clin Research right up front around the talks of COL Ohrt and COL Magill before the rest of the talks. For those who have not worked in this world before, that would set the stage for better understanding throughout the orientation and project selection.